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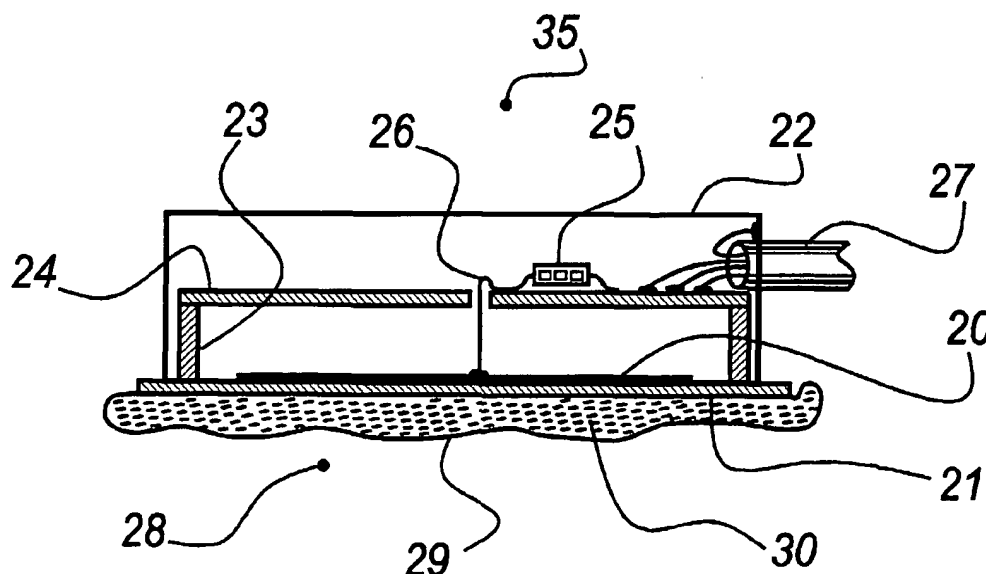
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(54) Title: ENHANCED PICKUP BIO-ELECTRODE



(57) Abstract: A bio-electrode (35) for obtaining ECG's and EEG's is enhanced by a cushioning layer (30) placed intermediate the body (3) and electrode (35). This layer (30) can carry and release water or moisture into the electrode-to-body interface. Moisture provided to this interface is ionically conductive, reducing tribo-electric noise. A bio-electrode so enhanced can obtain signals through clothing.

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TITLE:        ENHANCED PICKUP BIO-ELECTRODE

FIELD OF THE INVENTION

              This invention relates to electrodes for bio-electric field  
5 sensing. In particular, it relates to electrodes for electro-  
cardiograms (ECG), electro encephalograms (EEG), heart rate monitoring  
systems and the like.

BACKGROUND TO THE INVENTION

              Electrodes for the pickup of bio-electric signals can be  
10 categorized as being either ohmic or capacitive. Ohmic electrodes are  
resistively coupled to the body. Capacitive electrodes are  
capacitively coupled. Almost all bio-electrodes presently in use are  
ohmic. Ohmic electrodes may further be classed as 'gel' electrodes if  
they utilize an electrolytic gel, jelly, or paste which is placed in  
15 contact with the skin during use to maximize electrical coupling to the  
body.

              Many types of gel electrodes are disposable and possess  
self-contained gels in the form of 'solid' gel or 'wet' gel structures.  
These have limited shelf life, are not re-usable because the  
20 electrolytic gels tend to be fragile, sticky, and susceptible to drying  
out after exposure to air. Further, these types of electrodes utilize  
strong skin adhesives to ensure that intimate coupling to the body is  
established. Other types of gel electrodes, such as suction cup  
electrodes, require the user to smear electrolytic gel or paste on the  
25 electrode prior to each application and are inconvenient for this  
reason. Suction cup electrodes are also incompatible with free body  
movement.

              'Gel-free' electrodes, sometimes called 'dry' electrodes,  
have been proposed for re-usable electrode applications. Such  
30 electrodes can be used with electrolytic gels or pastes but can also  
be used without gels or pastes via simple mechanical contact with the  
skin. Gel-free use is attractive because it avoids the need for  
adhesives, fragile gels, or manual gel application.

              Dry electrodes of the prior art occur in two functional  
35 categories: ohmic and capacitive. Dry ohmic electrodes obtain  
body signals by direct contact between a conductive element and

the skin. Capacitive electrodes obtain body signals via electrostatic induction or 'displacement currents' which are mediated through an insulating layer positioned between the body and a conductive element that serves as a capacitor plate. Typically, the insulating layer is  
5 intimately bonded to the conductive element in a way that precludes ohmic contact between the conductive element and the body.

While the present invention is, in one variant, particularly suited for use with capacitive electrodes, it is also applicable for use with dry ohmic electrodes. The invention relates  
10 to an improvement over the prior art in the form of a body-engaging electrode interface which improves the coupling between bio-electrodes and the body.

Capacitive electrodes of the prior art were designed for operation via direct contact between the electrode dielectric and the  
15 skin. Prior art electrodes generally possess insulating (dielectric) layers with smooth, hard surfaces. In the past, the selection of materials for the insulating layer of capacitive electrodes was restricted by the perceived requirement of achieving a high value of capacitive coupling to the body. The nominal capacitive coupling  
20 between the electrode and the body is given by the approximate relationship  $C=eA/d$  where  $C$  is capacitance,  $e$  is the dielectric constant of the insulator,  $A$  is the area of the electrode, and  $d$  is the thickness of the insulator. This formula shows that a high value of capacitive coupling may be obtained using a thin insulating layer and  
25 an intimate degree of coupling to the body.

In order to accomplish a high capacitive coupling, prior art capacitive electrodes were restricted to the use of specialized insulating materials which could be deposited, sputtered, grown, or otherwise intimately bonded to the electrode conductive element as a  
30 thin, homogenous, contiguous, impermeable and stable dielectric layer. Dielectric materials used in prior art technologies have been typically hard, brittle and non-moisture absorbent such as glass, aluminum oxide or tantalum oxide. Other insulating materials used in the prior art include films such as Mylar films which are moderately flexible but  
35 these suffer the drawback of mechanical instability in the electrode-

to-body coupling resulting from the surface hardness and smoothness of the insulating layer. Such prior art electrodes are not self-stabilizing in their mechanical contact with the body and tend to slide on dry skin or hairy skin. This causes noise in the output signal.

- 5 Although prior art electrodes were not premised for use on clothing, the above problems are even further magnified when attempts are made to utilize such capacitive electrodes over clothing fabrics.

Capacitive electrodes of the prior art possess a further, and fundamental drawback related to the thinness of their dielectric  
10 layers. The main reason for signal degradation with prior art capacitive electrodes is that the intervening layers are electrically equivalent to the presence of a 'parasitic' capacitance placed in series between the electrode dielectric and the signal source. For prior art capacitive electrodes with thin dielectric layers this  
15 parasitic capacitance can easily dominate the electrode-to-body coupling.

For example, clean, dry, matted chest hair beneath an electrode can easily create a gap of 0.1mm with effective dielectric constant of approximately one. This is equivalent to a parasitic  
20 capacitance of approximately 9pF/cm<sup>2</sup>. The dry horny layer of the skin (stratum corneum) can typically create parasitic capacitances in the range of 50pF/cm<sup>2</sup> to 100pF/cm<sup>2</sup> depending on the age of the skin, its moisture content and the skin type. All the above parasitic capacitance values are smaller than the nominal capacitance values of  
25 typical prior art capacitive electrodes i.e. which range between 100pF/cm<sup>2</sup> to 10<sup>4</sup> pF/cm<sup>2</sup> with many examples even higher.

Because series capacitor networks are dominated by the smallest value capacitor, the net electrode-to-body coupling for typical prior-art electrodes with thin dielectrics applied on dry or  
30 hairy skin often approximates to the parasitic capacitance value and not the electrode nominal capacitive value. This has been problematic because the sensor electronics associated with prior art capacitive electrodes are premised in its design on there being a fixed, predictable and substantial capacitive coupling to the body. Any  
35 departure from this expected coupling value results in loss of signal

amplitude and loss of low-frequency response. Even with intimate contact to hairless skin, unpredictable changes in capacitive coupling of prior art electrodes can result from the build-up of sweat or moisture in the skin horny layer. For similar reasons, the net  
5 coupling can be pressure-dependent and motion-sensitive. Such effects have greatly limited the use of prior art capacitance electrodes with thin dielectrics. Similar disadvantages arise in prior art capacitive electrodes with extremely high dielectric constants and their correspondingly designed electronics.

10 As a separate phenomenon, both capacitive and ohmic dry electrodes suffer from noise when applied on dry skin or hairy skin. This is believed to be due to changes in resistance and to resistive (current) noise in the contact between the electrode and the body, and to noise generated by static charges arising from the mechanical  
15 contact between the electrode and the hair or dry skin with which it is placed in contact. Triboelectric noise also arises when attempts are made to obtain signals using capacitive electrodes over clothing fabric. This noise voltage can easily be orders of magnitude larger than the desired body signal and noise from this source can be highly  
20 motion sensitive.

Triboelectric noise is usually the most significant noise factor in high-impedance sensors used in conjunction with capacitive electrodes. However, and in contrast, ohmic electrodes suffer from noise induced by electrochemical phenomena called 'Nernst potential'  
25 or 'half-cell' or 'battery potential' effects. This refers to the molecular, charged bi-layers which are spontaneously created at any interface between a metallic conductor and an electrolyte. These effects are a source of both spontaneous and motion-induced noise arising as a result of chemical reactions and mechanical disturbances  
30 at the electrode-to-skin interface. Body fluids such as sweat are electrolytes i.e. their conductivity arises from ionic electron mobility.

Traditional ohmic 'gel' electrodes typically possess a conductive element with a silver chloride coating which is embedded in  
35 a viscous electrolytic gel. The gel serves as an electrolytic layer

which prevents direct contact between skin and any metallic elements thus avoiding the formation of an unstable skin-to-metal 1/2-cell in favour of a stable 1/2-cell at the chloridated metal-to-gel interface. The latter interface is electrically and mechanically stabilized by virtue of its stable local chemistry and its physical confinement within the chloridated metal coating and surrounding gel. Intimate contact of the gel with the body is maintained by a surrounding strip of adhesive which further minimizes the disturbance of the body-to-gel and gel-to-metal interfaces. The use of such adhesively stabilized gel electrodes is uncomfortable for patients subject to long-term ECG monitoring and is impractical in pre-formatted arrays of electrodes, and for electrodes which must operate re-usably by simple mechanical contact between electrode and the body. Furthermore, conventional gel electrodes are not practical for use over clothing.

15           A need exists for a bio-electrode possessing a body-engaging layer which is both comfortable and which provides stable pickup of body electric signals. This electrode layer should be self-stabilizing i.e. non-slippery on the body without the need for adhesives. Preferably, it should be sufficiently soft to conform to small-scale body features such as skin irregularities and hair and to provide a cushion against motion. The layer should also be, according to the invention, moisture absorbing when dry and moisture emanating when wet. This enables the layer to moderate changes in the moisture arising between the electrode and the body as would be induced by sweating. 25 This moisture 'buffering' property helps to minimize sweat-induced changes in interface capacitance and resistance, and sweat-induced 1/2-cell potential effects in the case of metallic components. Moisture emanated from the moistened layer also serves to shunt parasitic interface capacitances resulting from dry skin, hair, or clothing layers and to quench triboelectric effects.

Electrodes possessing special moisture-containing layers are known in the field of transdermal drug delivery (iontophoresis). Electrodes of this type rely upon an applied current to cause the migration of pharmaceutical particles through the epidermis. To facilitate this process, electrodes have been proposed that possess a

permeable interface saturated with liquid, typically an ionic water-based solution. Examples include: U.S. 5,087,242 to Petelenz et al 5,645,527 to Beck 5,281,287 to Lloyd et al 5,795,293 to Carim et al. While such electrodes possess a water-activated layer at the electrode-skin interface, these technologies are not employed to receive signals from the body. The present invention addresses the objective of an improved bio-electrode for use in sensing electric fields originating from inside the body.

The invention in its general form will first be described, and then its implementation in terms of specific embodiments will be detailed with reference to the drawings following hereafter. These embodiments are intended to demonstrate the principle of the invention, and the manner of its implementation. The invention in its broadest and more specific forms will then be further described and defined in each of the individual claims which conclude this Specification.

#### SUMMARY OF THE INVENTION

According to one aspect of the invention an electrode is fitted with a coupling layer on the body-facing surface. In the case of a capacitive electrode, this layer is placed against the dielectric surface of the electrode. In the case of an ohmic electrode, the layer is placed in contact with the conductive surface which may optionally be chloridated, and which conveys signals to the sensing circuitry. The coupling layer possesses a softness and texture which establish a comfortable engagement to the body while acting as a cushion or shock absorber minimizing mechanical motions at the interfaces between the body and the layer, and between the layer and the electrode components remote from the body inter-face. The coupling layer preferably has moisture carrying capacity and the ability to release water into the electrode to body interface. It is also desirable that the enhancement layer have the capability of "buffering" changes in the moisture state existing at the interface. When moistened with ionically conductive liquids such as ordinary tap water possessing ordinary ionic impurities, or saline solution or the like, the layer

is able to support a stable pathway for spontaneous ionic conduction between the body and the body-facing surface of the electrode.

For brevity in what follows the coupling layer will be called the 'enhancer' or 'enhancement layer' and a capacitive electrode  
5 possessing an enhancer shall be called an 'enhanced capacitive' electrode.

The mechanical properties of the enhancer allow it to stabilize the mechanical coupling between the electrode and the body by engaging with small-scale body curvatures, hair, and surface skin  
10 features. The moisture-carrying capacity of the enhancer provides it with the ability to absorb, store, and evolve moisture thereby ensuring delivery, preferably in an even distribution, of moisture between the electrode and body. When moistened the layer can emanate moisture into the electrode-to-body interface, thus quieting tribo-electric noise and  
15 improving the electrical coupling between the electrode and the body signal source when applied on dry skin, hairy skin, or over clothing.

The desirable electrical features of the enhancer are that it be substantially conductive when moistened i.e. that it displays a bulk resistance less than 10 Mohm and preferably less than several  
20 Mohm. This conductivity may be permanent or may be induced by the addition of ordinary water, electrolytes such as saline solutions, or by the presence of ambient moisture or sweat. The enhancer's mechanical conformability and electrical conductivity serve to create an ohmic link between the body signal source and the electrode. In the  
25 case of capacitive electrodes the enhancer serves to shunt parasitic interface capacitances arising from the horny layer of the skin and from any hair, clothing fabric and air gaps. This helps to stabilize the net capacitive coupling between the electrode and the body over time and ensures that this coupling is nearer to the nominal  
30 capacitance of the electrode independently of parasitic capacitances arising from dry skin, hair, and clothing.

By way of analog, whereas prior art capacitive electrodes are, in essence, simple capacitors for bio-potential pickup, enhanced capacitive electrodes of the present invention might be seen to be in  
35 the nature of padded electrolytic capacitors for bio-potential pickup



wherein the padded (enhancement) layer possesses conductivity sufficient to present the desired body signal evenly to the electrode dielectric layer while at the same time interfacing comfortably with the human body.

5           As the enhancer's conductivity is derived from ionic conductivity eg. via ions or charged-carrying impurities, noise-inducing electrochemical potentials at the enhancer-to-body interface are avoided or reduced. The conductivity of the enhancer can arise temporarily merely as a result of added moisture particularly when  
10 salts or ions are already present in the enhancer. A preferred embodiment employs an enhancer containing a highly absorbent material such as a super-absorbent, water-releasing polymer to slowly release an effective quantity of moisture into the body-to-electrode interface.

          In the preferred case, the enhancer layer is intimately  
15 bonded to, or incorporated into the structure of the capacitive electrode insulating layer. One example in the case of a capacitive electrode is an enhancer that is permanently glued or fused onto an already present insulating layer. Another example is a pre-fused enhancer-insulator structure manufactured as a single unit such as a  
20 sponge or a flocced fabric with an impermeable insulating backing such that the insulating backing can be used as the actual electrode insulating layer and the sponge or fabric is used as the enhancer.

          As another embodiment of the invention, an enhanced capacitive electrode or pickup system can be constructed as two  
25 autonomous, independent units - i.e. as a plain capacitive electrode or electrode array and as a separate enhancer or enhancer array which is manually positioned between the non-enhanced capacitive electrode array and the patient's body by the user. Such an enhancer may be held in position against the electrode by a positioning means such as a  
30 fabric pocket, or by an adhesive applied between the enhancer and the electrode dielectric layer. This allows for low-cost, re-usable or disposable 'peel-and-stick' type of enhancers which are hygienic.

          Examples of useful enhancer materials include conventional fabrics such as cotton denim, rayon, satin-finished polyester and other  
35 equivalent materials. A fabric enhancer layer can be intimately bonded

to a pre-existing capacitive electrode insulating layer by way of either a conductive or insulating adhesive. Both electrolytic adhesives and electrically insulating adhesives prove favourable. The resulting enhanced electrode surface possesses a surface texture which provides grip and which accommodates small scale body irregularities e.g. skin imperfections and hair. A fabric-based enhancer will be moisture-absorbing when dry and moisture-emanating when wet, enabling it to be used either wet or dry as required. Advantageously, but not necessarily, the fabric enhancer can be pre-treated with an electrolyte as by soaking it with an electrolytic solution and then drying it to leave a salty residue and render it more conductive when wetted. Useful electrolyte solutions include but are not restricted to a mild solution of sodium chloride, magnesium chloride, lithium chloride or mixtures thereof with appropriate ionic conductivity and deliquescent properties.

As an added benefit the enhancer, between its respective interfaces can be sufficiently compliant to allow small shifts in the relative positions of the body and electrodes interfaces to occur without giving rise to undue disturbance of the mechanical connections that would otherwise create noise. In effect, the enhancer can serve as a cushion between these two interfaces.

A preferred variant of the invention which is useful for the pickup of bio-electric signals of both the ohmic and capacitive types is based on an enhancer that contains a highly water-absorbing material or matrix. Preferred moisture carriers are the super water-absorbent co-polymers sometimes called 'super-absorbent hydro-gels' which are based on cross-linked sodium or potassium polyacrylate / polyacrylamide (CLP). These are made available in granular form as for example by the Terawet company. An enhancer consisting of CLP granules contained in a cloth bag or pouch can be wetted with ordinary tap water to render it cushion-like, moisture emanating, and possessing sufficient conductivity to manifest all the electro-mechanical features required to realize the advantages of the invention i.e. softness, signal stabilizing effects, and noise reduction. Once saturated, the CLP has the advantage of releasing moisture in a slow, controlled manner and

over long periods of time. Although CLP is a preferred variant, the moisture containing matrix may be comprised of any type of sponge or porous material or carrier that will absorb water when dry and slowly release water when wet.

5                   When used with a capacitive electrode applied over clothing, moisture from the enhancer can penetrate clothing layers and provide a conductive bridge between the body signal source and the capacitive electrode elements - i.e. thereby shunting the parasitic interface capacitance arising from the clothing and from dry skin or hair beneath  
10 it. In some cases on skin this shunting effect can be accomplished mechanically, that is to say, purely as a result of the softness and intrinsic conductivity of the enhancer without the need for added moisture. This stabilizes the coupling of a capacitive electrode to the body while reducing triboelectric noise at the electrode-to-body  
15 interface by reducing motion and by providing a discharge pathway to the body for local accumulations of charge.

                  The application of the invention is facilitated by employing a capacitive electrode sensing system with a very low input capacitance. This enables the use of a low capacitance coupling to the  
20 body with advantages as next described.

                  It has been found, as described in PCT application PCT/CA00/00981, the contents of which are adopted herein by reference, that a capacitive pickup electrode system may be advantageously operated in the low-capacitance region of the relationship  $C=eA/d$  where the  
25 capacitance  $C$  is relatively insensitive to variations in separation gap  $d$ , - e.g. a 0.1 mm displacement of the electrode causes less than a 50 percent change in  $C$ . An electrode system may be operated in this range by providing an electrode and sensing circuit designed to operate in the low capacitive coupling regime, such an electrode may have a  
30 dielectric layer with a low dielectric constant and a relatively increased thickness - e.g. 0.1mm to 1.0mm. Alternately, a series capacitance of low value - e.g. 5 to 40 picoFarads can be placed in series with the pickup electrode in its connection to a high impedance input amplifier circuit.

This arrangement enables use of arbitrary dielectric materials as opposed to highly specialized dielectrics as in the prior art. This decreases the signal sensitivity to variations in individual electrode characteristics and allows greater scope in the selection of  
5 electrode dielectric materials and manufacturing processes. In contrast to the prior art which was restricted to using specialized dielectrics, a much greater variety of dielectrics can now be used due to low-coupling demands placed on the pick-up electrode. Capacitive electrodes can be made flexible by using highly flexible dielectrics.  
10 These can provide a more stable contact and comfortable fit on the body. Unlike the prior art, capacitive electrodes employed under the invention can be made more robust and scratch-resistant by using stronger or thicker dielectrics. Operation in a low-coupling regime enables enhancers to be bonded or adhered to the capacitive electrode  
15 dielectric by use insulating bonding agents and adhesives without causing a degradation in the electrode behaviour.

A further benefit of using a capacitive electrode sensing system with very low input capacitance is that signal pickup is possible with a relatively low level of intimacy of contact to body.  
20 As described in the introduction, this is due to the fact that low-coupling electrodes with relatively thick dielectrics can possess nominal capacitance values that are lower than the typical parasitic capacitances on the body thus remaining relatively insensitive to the presence of dry skin, hairy skin, or clothing. Such electrodes can  
25 also remain insensitive to temporal effects of sweat permeation into the horny layer. Operation in the low-coupling regime also allows for the acquisition of signals through clothing fabric layers and facilitates the use of enhancement layers of the present invention.

Appropriate realizations of the invention can be used to  
30 construct heart-rate and ECG electrodes capable of obtaining signals in locations not practical with non-enhanced capacitive or conventional ohmic electrodes. This includes over-clothing pickup, waist level pickup, pickup from the ear, as for example, if electrodes of the invention are built into ear-phone cushions, and pickup from other body  
35 parts such as the back or the shoulders when electrodes of the

invention are placed under or built into straps, backpacks, belts, or clothing-like supports.

In this manner, a bio-electrode system may be provided that is convenient and comfortable for the user, and less susceptible to  
5 disruption from noise.

The foregoing summarizes the principal features of the invention and some of its optional aspects. The invention may be further understood by the description of the preferred embodiments, in conjunction with the drawings, which now follow.

#### 10 BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1A is a combined pictorial/electrical schematic depiction of a single pick-up of the invention in position adjacent to a body whose electrical field is to be sensed. The voltage divider network is capacitively coupled to the body at both ends and drives an  
15 operational amplifier.

Figure 1B is a conventional electrical schematic corresponding to the input portion driving the amplifier of Figure 1A.

Figures 1C and 1D are the schematics of Figure 1A and 1B with the added presence of a series capacitor in the amplifier input.

20 Figure 2A is Figure 1A with the substitution of a resistive, conductive coupling to the body at one end of the voltage divider network.

Figure 2B is a conventional electrical schematic corresponding to Figure 2A.

25 Figure 3 is an electrical schematic for a dual pick-up electrode configuration, based on the pick-up of Figure 1A, with signals being fed to a differential amplifier, but with dual, parallel Schotkey diodes as input leakage resistors.

Figure 4 is an expanded electrical schematic of the circuit  
30 of Figure 3 with the additional presence of an amplifier and optical coupler to provide electrical isolation.

Figure 5 is a graph showing the change of capacitance of pick-up electrodes with various surface areas as a function of separation distance for the electrodes.

Figure 6 is a graph showing the percentage change in capacitance for a 0.1 mm change in electrode-to-body gap distance as a function of nominal electrode-to-body gap distance over a range of 0.0 to 1.0 mm, assuming the body acts as a perfect electrode.

5        Figure 7 is a plan view of an electrical circuit corresponding to Figure 4 laid-out in a belt to be worn over the chest of a patient.

Figure 8 is a pictorial depiction of the belt of Figure 7 in place over the chest of a patient.

10       Figure 9 is a pictorial version of a garment worn by a patient that carries four pick-up electrodes.

Figure 10 is a graph of total effective coupling capacitance between the sensed body and the input to the amplifier of the sensor, plotted as a function of the separation distance of the electrode from the surface being sensed. Three curves are shown, two with a limiting series capacitor present and one with no limiting capacitor present.

15       Figure 11 is similar to figure 10 but with the vertical scale for the input capacitance increased by a factor of ten and showing one curve with and one curve without a limiting capacitor present.

20       Figure 12 is a cross-sectional side view of a capacitive electrode with on-board electronics equipped with an enhancer or enhancing layer according to the invention positioned at the body interface for the electrode.

25       Figure 13 is a graph of the approximate signal to noise ratios for enhanced capacitive electrodes, both pre-moistened and ostensibly dry, as a function of increasing numbers of layers of a cotton T-shirt fabric over the skin of a human body.

30       Figure 14 is a graph of R-peak amplitude seen in the same data set used for Figure 13 i.e. for enhanced capacitive electrodes, both pre-moistened and ostensibly dry, as a function of increasing numbers of folded layers of cotton T-shirt material over human skin.

Figure 15 is a dual, real-time display comparing differential ECG-like signals obtained using two pairs of electrodes placed side-by-side on the unprepared skin of a test subject and held in position using an elastic strap. The pickup geometry was an approximate MCL<sub>3</sub> configuration employing right sub-clavian and V<sub>4</sub>,

electrode sites. The bottom trace shows the conventional wet-gel electrode signal while the top trace shows an un-enhanced low-coupling capacitive electrode signal. Nominally identical differential amplifiers were used for each electrode pair.

5           Figure 16 is a graph showing a differential pickup signal obtained by placing enhanced capacitive electrodes with moistened enhancers held in place by a chest belt over unprepared skin of a test subject. The electrodes were held in position several centimeters  
10 strap placed around the chest. Electrodes were connected to the lead-one inputs of a commercial ECG machine. All other ECG inputs were grounded to the subject body-reference via a stainless steel plate at the right foot.

          Figure 17 is a graph of the chest-belt configuration of  
15 Figure 16 but showing enhanced capacitive signal pickup over an initially dry, woven cotton golf-shirt covering the skin of a human body.

          Figure 18 is a graph as in Figure 17 showing pickup using an ostensibly dry enhancer over a dry cotton golf-shirt covering the  
20 skin of a human body.

          Figure 19 is a graph showing a signal obtained over a dry, cotton golf-shirt covering the skin of a human body using an unenhanced capacitive electrode operating in the low-coupling regime. The electrode dielectric was ordinary electrical-grade fiberglass circuit-  
25 board of thickness 0.74mm.

          Figure 20 is a graph obtained in the chest belt configuration described in Figure 16 but showing the signal approximately 5 minutes after placing ohmic electrodes made of conductive rubber directly on unprepared skin. For the first  
30 approximately 5 minutes no signal was seen.

          Figure 21 is a graph obtained in the chest belt configuration described in Figure 16 but showing the differential signal obtained using two enhanced ohmic electrodes. The electrodes were identical conductive rubber as before but with an enhancer layer  
35 constructed of a textile pouch filled with super-absorbent polymer granules fastened to the rubber. The enhancer was soaked with ordinary tap water and subsequently blotted with a towel.

Figure 22 is a graph as in Figure 21 but with the enhanced ohmic electrodes placed over a cotton T-shirt covering the skin of a human body. A signal, as depicted, very similar to that shown in Figure 21 appeared approximately 2 minutes after placing electrodes on the clothing layer.

Figure 23 is a graph as in Figure 20 but with the un-enhanced ohmic electrodes placed over a dry cotton T-shirt over the skin of a human body. No ECG signal was evident but only 60Hz artifact and noise.

Figure 24 is a graph as in Figure 16 taken with a pair of enhanced capacitive electrodes with moistened enhancer placed over a hydrophobic polyester fabric layer over the skin of a human body. The settling of the signal can be seen as a result of the moisture penetration from the enhancer into the clothing fabric.

Figure 25 is a graph as in Figure 24 taken through a cotton fabric over the skin of a human body and showing a relatively rapid settling time.

Figure 26 is a revised version of Figure 1B wherein the presence of an enhancer layer, together with the skin and small air gaps are modelled by parasitic resistance  $C_{pa}$  and resistance  $R_{pa}$  in parallel.

#### DESCRIPTION OF THE PREFERRED EMBODIMENT

While aspects of the invention are suited for use with conventional electrodes of both the ohmic and capacitive type, a special type of preferred electrode will first be described before addressing the electrode enhancer of the invention.

In Figure 1A a pictorial schematic is shown of an electrical sensor system for a capacitive ECG sensor incorporating a pick-up electrode 1 in the form of a flat conductive surface placed adjacent a first location 2 on a body 3 where an electrical signal is to be sensed originating from an electrical signal generator 4 within the body 3 that provides a source voltage  $V_s$ . The pick-up electrode 1 develops a capacitive coupling to the body 3 through an intervening dielectric layer separating it from the body 3. This capacitive



coupling for the pick-up electrode 1 is represented schematically by the capacitor  $C_p$ .

The electrode 1 is connected to the input of an operational amplifier - IC1A, or its equivalent such as a field effect transistor.

- 5 Input resistance  $R_i$  connected between the amplifier input and circuit ground has a resistance value of on the order of  $10^{12}$  ohms and serves to discharge the input of DC offsets and restore proper voltage input levels while accepting signals of the desired frequency.

- The output  $V_o$  from the voltage divider network which drives  
10 the operational amplifier IC1A is measured across input resistor  $R_i$  that extends between the input of the operational amplifier IC1A through circuit ground to a reference capacitor  $C_r$  that is coupled to the body 3 at a second, separate location 5. This location 5 may be separated from the first location 2 in obtaining conventional ECG  
15 signals. The locations 2,5 may also be proximate, e.g. adjacent, at certain body locations and still provide useful signals.

- Capacitive coupling  $C_r$  is effected by means of an electrode (not shown in Figure 1A) that is separated from the body 3 by a non-conducting material that acts as a dielectric. Conveniently, the case  
20 for an on-board battery holder can serve as this electrode, as shown further below.

- The nature of the dielectric material has little effect on the pick-up obtained by capacitive electrodes operating in low-coupling regime and for electrodes of the present invention in which an enhancer  
25 prevents direct contact between the electrode dielectric and the body. In each case, electrodes can be placed in 'casual' mechanical contact with the body being sensed as in the case of ECG pick-up on hairy skin or over clothing. Satisfactory values of dielectric constant for the dielectric layers have been found in the range 1 to 10. Compared to  
30 prior art, a much greater variety of flexible, non-brittle dielectrics can therefore be used. A further advantage of low-coupling capacitive electrodes is that electrodes with thick dielectrics can be more robust compared to prior art thin-film dielectrics.

- Inside the body 3, the signal generator 4 is seen as being  
35 subject to internal resistance  $R_b$  within the body 3.

The input portion of circuit of Figure 1A is redrawn as Figure 1B in more conventional form. In Figure 1B, the capacitance  $C_o$

arises from the combined input capacitance of the operational amplifier IC1A and the input resistor  $R_i$  and due to geometrical capacitances arising between the circuit, the electrode and the shielding elements. The total apparent input resistance of the amplifier is represented by

5  $R_o$ , including the resistive value of the input resistor  $R_i$ . Collectively, the capacitances  $C_p$ ,  $C_o$ ,  $C_R$  act as a voltage divider network whereby the output voltage  $V_o$  is proportional to the source voltage  $V_s$ .

In Figures 2A and 2B, the coupling to the body 3 at the end of the voltage divider network opposite to the pick-up electrode 1, is effected principally by a direct, conductive contact. The resistance of the interface is indicated by  $R_R$ . Necessarily, some slight capacitance coupling is also still present, indicated by  $C'_R$ .

10

The output signal of the sensor is extracted by measuring the voltage difference across an electrical component in the voltage divider network that is connected to the subject electrical source.

15 This should be done through a high impedance, low capacitance sensing circuit or sensing means to minimize signal loss. A field effect transistor or operational amplifier having an input impedance of on the order of  $10^{14}$  ohms and an input capacitance of about 3 to 5 picofarads

20 has been found to be satisfactory when the other capacitor(s) in the voltage divider network have values of on the order of 10 picoFarads. Signals can be obtained with a circuit signal sensing means having an effective input capacitance of on the order of 15 to 20 or 25 picofarads. The lower the input capacitance, the less signal loss

25 occurs. It is preferable that the electronic circuit sensing means have an input capacitance of less than about 25 picofarads, preferably less than 15 picofarads, more preferably less than 10 picofarads. Used in conjunction with a pick-up electrode having an area of on the order of one to ten square centimetres, dielectric media having a total

30 effective dielectric constant of 1-10 and a body-to-surface gap distance of on the order of 0.1 to 4 millimetres, signal values of the order of 1 millivolt or less may be detected from the skin surface of the human body.

With this type of sensor configuration useful signals may

35 be obtained with the plate of the pick-up electrode separated from the skin or sensed body by a gap that allows the pick-up to qualify as a "low-coupling" electrode. By operating the sensor in the

capacitance/gap separation region specified hereafter, variations in skin properties, sweating, body motions, will not detract inordinately from the signals being obtained.

A pickup electrode that is removed somewhat from the electrical field source is able to supply a satisfactory signal by reason of the mathematical relationship that exists between the value of capacitance and the separation distance existing between capacitor plates or electrodes. Since capacitance varies inversely with separation, the mathematical form of a curve for capacitance value plotted against separation distance is in the shape of a hyperbola. This means that the capacitance performance of a pickup electrode can operate in two distinct regions:

- 1) a first region wherein the separation distance is small and the curve is steep, corresponding to the situation in the prior art where the capacitance value will vary highly, with great sensitivity, in response to small changes in the separation distance; and
- 2) a second region wherein the separation is greater, the curve is relatively flat, and the capacitance value varies relatively insensitively with similar changes in the separation distance or body surface layer.

For the purposes of the present invention, the preferred region of operation according to one variant of the invention is in the second, separation-insensitive zone.

In Figure 5 a graphic plot is depicted of the variation of capacitance  $C$  with a variation in the separation distance  $d$  at various separation distances  $d$ , based upon the theoretical formula:

$$C = e.A/d$$

where:  $C$  is the effective capacitance of, for example  $C_p$ ,  
 $d$  is the separation distance of the electrode plate from the body giving rise to the capacitance,  
 $A$  is the area, or effective area, of the pick-up electrode 1; and  
 $e$  is a proportionality constant determined by the dielectric constant of the material in the separation gap.

In Figure 5 the value of the dielectric constant is assumed to be that of air, i.e. 1.0 and the plates forming the capacitance are assumed to

be fully conductive. This is therefore an idealized variant on the case of coupling to the human body.

Four curves are shown in Figure 5 for pick-up electrodes 1 having surface areas as follows:

$$\begin{array}{ll} 5 & a = 1 \text{ cm}^2 \qquad c = 50 \text{ cm}^2 \\ & b = 10 \text{ cm}^2 \qquad d = 100 \text{ cm}^2 \end{array}$$

Each capacitance curve can be separated into two important regions: region 6, in which the capacitance changes relatively rapidly with a given change in separation distance; and region 8 in which the capacitance changes relatively slowly with a similar given change in separation distance. These regions are generally separated on Figure 5 by boundary line 7. For a capacitor with an electrode area of 1 cm<sup>2</sup>, the line 7 passes approximately through a capacitive value of about 40 picoFarads. For capacitors with an electrode area of around 15 25 cm<sup>2</sup> and capacitive values below 200 picoFarads, region 6 approximately corresponds to the zone with  $d = 0.1$  mm or less; while for such values region 8 approximately corresponds to the values above  $d = 0.1$  mm. Note that 0.1 mm is approximately the thickness of human hair and can be considered as a separation gap typical of parasitic 20 capacitance on hairy skin.

An important implication of Figure 5 is that sensors designed to operate with capacitance values within regime 6 require a high degree of intimacy of coupling to body and are very sensitive to small additional changes in the separation distance ( $\Delta d$ ). Such 25 electrodes are also sensitive to changes in the electrical properties of the skin and its parasitic capacitance as may arise, for example, through variations in the amount of sweat present. In contrast, sensor systems with capacitance values corresponding to region 8 and corresponding electronics are relatively insensitive to body coupling and to such changes. This is illustrated more succinctly in Figure 6. 30

These factors can be conveniently summarized by way of considering the sensitivity of the electrode coupling value to small changes in separation distance  $d$ . In Figure 6, the percentage change in capacitance corresponding to a  $\Delta d = 0.1$  mm is graphed as a 35 function of the nominal separation distance  $d$ .

Figure 6 is dimensionless along the C axis and applies to all capacitive sensors which obey or approximately obey the relation

$C=eA/d$ . A preferred application of enhancement layers according to the invention is based on capacitive sensors which when employed, are designed to operate in region 8' of Figure 6, as opposed to region 6' from which it is separated by boundary line 7'. In this former regime  
 5 8' the capacitance, and hence the output signal is sufficiently insensitive to spatial body surface variations so as to contribute to the advantages of signal stability.

Figures 5 and 6 premise that operation in regions 6 and 6' can be effected by achieving, or tolerating, low capacitance coupling  
 10 between the body and the pickup electrode. Figures 10 and 11 apply to an alternate case wherein the capacitive coupling between the pickup electrode and the body is high, but the results of achieving system operation in preferred regions 6,6' is still obtained. This is achieved by insertion of a series limiting capacitor  $C_L$  in the input to  
 15 the first stage amplifier of the sensor.

This series limiting capacitor may have a preferred value that is greater than the input capacitance of the first stage amplifier, and less than the effective value of the capacitance coupling between the pickup electrode and the body whose electrical  
 20 field is being sensed, e.g. between 5 and 40 picoFarads.

In Figures 1A and 1B the pickup capacitor  $C_p$  is shown as being directly coupled to the operational amplifier 1C1A. In Figures 1C and 1D a series capacitor  $C_L$  is shown added between the pickup capacitor  $C_p$  and the amplifier input (at which  $V_o$  is detected). The  
 25 effect of this limiting capacitor  $C_L$  is to place a maximum value on the capacitance extending between the body 3 and the signal sensing means 1C1A. The pickup electrode's capacitance  $C_p$  is in series with the limiting capacitor  $C_L$ . Collectively, they behave as a single capacitor having a total net value  $C_T = 1/(1/C_L + 1/C_p)$ .

30 Figures 10 and 11 plot the behaviour of  $C_T$  as a function of the separation distance present for the pickup capacitor  $C_p$ . This net value capacitor  $C_T$  provides a more stable, separation-insensitive circuit performance that occurs in its absence. This is particularly true when  $C_L$  is smaller than  $C_p$ .

35 A convenient formula for establishing a value for  $C_L$  is that  $C_L$  should be less than 5 (picoFarads/cm<sup>2</sup>) times the area of the pickup electrode (in cm<sup>2</sup>).

The consequence is that a similar region 8" of insensitivity to displacement of the pickup electrode exists in Figures 10 and 11, parallelling regions 8 and 8' in Figures 5 and 6. A similar preferred criterion for performance of the invention can also be established for  
5 the circuit arrangement of Figure 1C, 1D, namely, a 0.1 mm displacement of the pickup electrode causes a 50% or small change in the net capacitance  $C_n$ . Preferably the change is less than 20%.

Thus the effect of desensitizing the signal pickup and coupling capacitance can sometimes be achieved through the presence of  
10 a limiting capacitor  $C_L$  in the input link between the pickup capacitor  $C_p$  and the signal sensing means 1C1A.

For the present invention, the input resistance present at the input to the high impedance amplifier can be provided from two sources:

- 15 1) the inherent input resistance of the amplifier, typically  $10^{13}$ - $10^{14}$  ohms;
- 2) the input resistance of an added, external, input resistor,  $R_i$  between input and reference voltage.

A preferred value for this resistance  $R_i$  may be determined by  
20 considering the pickup electrode and input resistance as an RC high frequency passing filter.

Assuming an effective pickup electrode capacitive value of 60 picoFarads and a low frequency cut-off of 0.05 Hz established by the RC input value of the first stage amplifier, a preferred value of  $4 \times$   
25  $10^{12}$  ohms may be provided for the input stage input resistance  $R_i$ .

Occasionally, the near-DC signals delivered to the pickup electrode will be so substantial as to drive the signal at the input amplifier to the limit of its range of response. When overdriven, the recovery period before a normal input level is established can be  
30 shortened by providing a special input resistor arrangement at the amplifier input. In such cases it is convenient to provide the input stage with a non-linear input resistance. This can be achieved by grounding the input through pairs of Schotkey diodes,  $D_1$ ,  $D_2$  in Figure 3, connected in parallel.

35 The forward resistance of Schotkey diodes before breakdown occurs can be on the order of  $10^{13}$  ohms. By choosing diodes with a forward breakdown voltage that is above the level of the signal of

interest, the "reset" function of the input resistance of the high impedance amplifier can be improved.

As the resistance of the Schotkey diodes prior to breakdown may be higher than the appropriate value to provide an input resistance  
5 suited to the given low frequency cut-off for the RC filter, such diodes  $D_1, D_2$  may have to be accompanied by a parallel input resistor  $R_i$  that establishes the appropriate net value for input resistance for small level signals.

In Figure 3 two pick-ups similar to that of Figure 1A  
10 (except for the substitution of diodes  $D_1, D_2$  for the input resistor  $R_i$ ) are used to drive a differential amplifier IC3A. The second additional pickup electrode 1A is placed at a location 10, separated from the first and second locations 2 and 5. Within the body the signal source  $V_s$  may be treated as distributing its potential over the  
15 resistors  $R_B, R'_B, R''_B$ .

By use of this differential signal detection circuit, common mode noise present in the two pick-up circuits will be minimized. In some cases the connection to location 5 through  $C_R$  may be omitted as a signal can be obtained from locations 2 and 10 only.

Figure 4 shows the circuit of Figure 3 extended by an  
20 optical isolator IS01 driven by an operational amplifier IC4A which is, in turn, driven by the output from the differential amplifier IC3A. By mounting these circuits as close as possible to the pick-up electrodes 1 1A, interference from ambient 60 Hz electromagnetic  
25 signals can be minimized.

In Figure 4, a shielding conductive layer 11 is depicted as overlying the externally-directed side of the circuitry. This layer/structure 11 is preferably connected to the circuit common point but need not necessarily be so connected. In some configurations this  
30 shield may be "floating". Its role is to exclude effects arising from intruding electro-magnetic signals, e.g. 60Hz, originating in the environment. In non-earthed applications the shield distributes ambient, intruding signals equally to both pickups thus contributing to common mode noise rejection. It is highly desirable that such a  
35 shield be employed in one or other of such configurations.

The "low-coupling" capacitive electrode as described has advantages over conventional ohmic and capacitive electrodes in that

it need not be intimately pressed or adhered against the body which is the source of the field being sensed. In fact, useful signals can be obtained with a loosely positioned pickup electrode, and even through some types of fabric. This opens-up possibilities for the long term  
5 monitoring of patient heart rate and ECGs without the use of uncomfortable adhesives found in typical existing ohmic electrodes.

While useful signals can be obtained directly through certain types of fabric, e.g. cotton, by using a low-coupling electrode according to the invention, noise has been found to be present in a  
10 variety of differing fabrics and environmental conditions. Noise is believed to originate primarily from tribo-electric effects that arise when surfaces touch or slide with respect to each other. A feature of the present invention is the inclusion of an "enhancer" layer between the electrode and the body that reduces the amount of noise occurring  
15 in respect of the sensed signal.

In Figure 12 an electrode 35 with on-board electronics has a conductive plate 20 covered by an insulative dielectric layer 21 and preferably encased with a shielding cap 22. To support the electronics, a circular ring 23 supports a board 24 that carries a high  
20 impedance input amplifier circuit 25. A lead wire 26 connects this circuit 25 to the plate 20. Output wires 27 carry the output from the circuit 25 to further circuitry (not shown).

Beneath the dielectric layer 21 is positioned an enhancer 28. The enhancer 28 is preferably positioned adjacent to the  
25 dielectric layer 21; more preferably it is bonded to the dielectric layer 21, as by an adhesive.

The enhancer 28 has a body-facing surface 29 which is a textile or the like that provides a relatively non-slippery engagement to occur between the enhancer 28 and a body 3. Cotton textile has been  
30 found to be suitable for this purpose. The enhancer 28 may optionally have a cushioning volume of material 30 present between the facing surface and the dielectric layer 21. This material 30 is preferably pliable or conformable, sufficient to cushion the electrode 25 against small displacements of the body 3 with respect to the electrode 35.  
35 Alternately, the textile itself may perform this function.

A preferred cushioning material is a granular assembly of super-absorbent polymer, e.g. cross-linked sodium or potassium



polyacrylate/polyacrylamide (CLP). A desirable characteristic of CLP which is a preferred feature of the cushioning material 30, is that it has the capacity to both contain and emit water. Further CLP, as a preferred characteristic for the cushioning material 30 is relatively  
5 conductive of electricity when moist, operating by ionic conduction.

When placed against skin of a body 3, CLP as the cushioning material 30 will evolve or emanate water by diffusion which will introduce moisture into the electrode-to-body interface. Water transferred from the CLP to the interface will be slightly ionically  
10 conductive as a result of contact with the CLP and with skin or clothing. Alternately or additionally, sweat will provide salt to the interface, thus raising the electrical conductivity of the skin-to-electrode interface.

Figure 13 is an illustrative graph showing the general trend  
15 for the approximate signal to noise ratio (SNR) for a signal obtained by an enhanced capacitive electrode over multiple layers of dry T-shirt fabric on the body. The layers were obtained by upwardly folding the T-shirt around the chest. The electrodes were held in position several centimeters below each nipple of the test subject by use of an  
20 elasticized fabric strap placed over the clothing fabric around the chest. Electrodes were connected to the lead-one inputs of a commercial ECG machine. All other ECG inputs were grounded to the subject body-reference via a stainless steel plate at the right foot.

The SNR was estimated by measuring average peak-to-peak  
25 voltages of the cardiac ventricular depolarization peak and the noise within the band 0.5Hz to 30Hz. The enhancer 30 is based on salted cotton denim adhered to the electrode dielectric. The signal to noise ratio is plotted against the number of layers of clothing T-shirt fabric, both for a water-moistened enhancer and for an ostensibly dry  
30 enhancer layer. In all cases the moistened enhancer provides a higher signal-to-noise. The SNR declines more rapidly for the ostensibly dry enhancer than for moistened enhancer as the number of layers of clothing fabric are increased.

Figure 14 is an illustrative graph based on the same  
35 measurement series as Figure 13, showing the general trend for the signal strength of the ventricular depolarization "R" peak as a function of the number of layers of cotton T-shirt between the

electrode of Figure 13 and skin. In this case, the moistened enhancer shows relatively little signal loss with an increase in the number of clothing layers while the ostensibly dry enhancer provides a reducing signal strength as the layers increase. This illustrates signal loss  
5 due to parasitic capacitance of clothing for a capacitive electrode operating in the low-coupling regime.

Figure 15 is a dual curve graph showing ECG signals obtained directly over unprepared skin for a pair of unenhanced capacitive electrodes, curve 50, and a pair of prior art 'wet-gel' ohmic pickup  
10 electrodes produced by the 3M company of Minnesota, curve 51. One electrode from each pair were positioned side by side on the body at approximate MCL3 locations. Each electrode pair provided signals to nominally identical electronic circuitry in differential mode corresponding to Figure 3, but with the high-impedance input stage  
15 bypassed for the ohmic electrodes. The capacitive electrode pickup represents an acceptable ECG signal although the capacitive electrode signal amplitude is only about 60% of the ohmic electrode signal amplitude for the particular devices used.

Figure 16 depicts the ECG graph obtained on skin with a  
20 capacitive electrode possessing a moist, salted cotton denim enhancer layer. The signal was stable and 100% of the signal amplitude predicted on the basis of the electrode nominal capacitive coupling.

Figure 17 is an ECG graph obtained with the enhanced capacitive electrode of Figure 16, moistened and applied over a single  
25 layer of a coarse woven cotton golf shirt. This signal is essentially the same as obtained directly over skin in Figure 16.

Figure 18 is a graph as Figure 17 wherein the enhancer layer has not been moistened. A loss of signal amplitude and an increase in noise is apparent.

30 Figure 19 is a graph as in Figure 17 but with no enhancer on the capacitive electrode. Without the enhancer layer there is a further reduction of signal amplitude and an increase in noise including significant baseline instability.

Figure 20 is a graph of the ECG signal obtained with a  
35 conductive rubber ohmic electrode applied directly on unprepared ostensibly dry skin after a 5 minute delay. Initially there was no signal. This electrode is a prior art pickup used for trans-cutaneous

electrical nerve stimulation (T.E.N.S.) and neural muscular electro-stimulation (N.M.E.S.) with its gel layer removed. The signal is unusable.

5 Figure 21 is a graph of an ECG signal obtained with an enhancer layer present over the electrode of Figure 20 as applied directly to the skin. The enhancer was a fabric pouch of cotton-polyester textile containing potassium based super-absorbent copolymer CLP granules which had been thoroughly wetted and then wiped surface dry. The signal was fully usable for ECG purposes.

10 Figure 22 is a graph as in Figure 21 with the signal picked-up through a single layer of cotton T-shirt after allowing a minimum of 2 minutes for the signal to stabilize. The graph shown is taken after approximately 10 minutes. As of 2 minutes, the signal was equivalent in amplitude and morphology to its final form as in Figure  
15 22, except that it was more sensitive to motion artifacts. Such artifacts disappeared after 5-6 minutes. On removal of the electrode the T-shirt fabric previously in contact with the electrode was not soaked with water but was cool and lightly damp.

Figure 23 is a graph of the signal obtained using an un-  
20 enhanced ohmic electrode as in Figure 20 applied to a body through a layer of the same cotton T-shirt fabric as utilized in Figure 22. No heart signal is present. Rather 60Hz and baseline noise dominates.

Figure 24 is a graph of an ECG curve obtained through polyester fabric showing the relative stabilization of the signal with  
25 time arising from moisture from a moisture-carrying and emanating cotton denim enhancer layer providing moisture to the body-to-electrode interface. As moisture builds up in the polyester fabric it contributes to the quenching of interface noise. No noticeable wet spot was visible on the fabric after 30 seconds, by which time  
30 stabilization of the signal had occurred. Only a cool, moist region was formed under the electrode. This signal was obtained between unprepared skin on the right forearm and the clothing-covered precordial V4 region through a differential pickup circuit of the type of Figure 3. Electrodes were held in position with elastic straps.  
35 A Burdick limb plate was used on the left wrist for body referencing. Ambient humidity was 34% and the temperature was 24°C.

Figure 25 is a graph similar to Figure 24 for a signal taken through a 100% cotton T-shirt fabric. Again, the signal settles with time as moisture rapidly penetrates the fabric of the T-shirt.

Figure 26 is a revised version of Figure 1B wherein  
5 the presence of the enhancer layer together with the horny skin layer (stratum corneum) and air gaps due to hair, etc. are modelled by parasitic resistance  $R_{pa}$  and capacitance  $C_{pa}$  in parallel. Through use of a conductive cushioning material with moisture-emanating properties such as CLP, values for  $R_{pa}$  can be reduced to the order of several  
10 Megohms or less. The capacitance value  $C_{pa}$ , while considerably larger than  $C_p$  becomes substantially irrelevant as a factor affecting signal pickup, once  $R_{pa}$  stabilizes at its minimum value through moistening of the skin.

It is preferable in order to minimize noise for signals in  
15 the range 0.05 Hz to 100 Hz that the time constant of  $R_{pa}$  and  $C_p$  be less than approximately 100 microseconds. A small electrode 35 such as shown in Figure 12 has been constructed with a nominal  $C_p$  of 28 picoFarads as measured with the electrode 35 placed over a copper plate. Values for  $C_{pa}$  typically range over 10-100 picofarads. With  
20 values for  $R_{pa}$  on the order of or below 10 megohm, the output signal  $V_o$  is relatively independent of frequency in the ECG band of 0.05Hz-100Hz.

In Figure 7 a belt 12 is depicted that carries the circuit of Figure 4. The hatched areas are decorative. The pick-up electrodes 1, 1A are mounted on a KAPTON<sup>(TM)</sup> film 13 that serves both as a spacer  
25 and as an insulating dielectric of approximately 0.13 mm thickness. The pick-up electrodes 1, 1A have been measured against a copper plate as providing a nominal capacitance value of 20 picoFarads.

The belt 12 of Figure 7 has its own on-board power supply in the form of batteries 14. The case 15 of the batteries 14 is  
30 connected to circuit commons which together constitute a 'floating' ground network. When placed on the skin a capacitive coupling arises between the ground network and the body thus providing the reference capacitor  $C_R$ . A measured value for  $C_R$  when placed against a copper plate of 160 picoFarads has been observed with the case 15 coupled to  
35 the entire circuit.  $C_R$  is not essential for differential pickup.

The substrate for the belt 12 is made of KAPTON<sup>(TM)</sup> having a thickness of 5 thousandths of an inch. This forms the principal

dielectric element for both of the capacitors  $C_p$  and  $C_R$ . The nature of the dielectric material has little effect on the invention when the pick-up electrode plates are located at a sufficient separation gap from the body as when an enhancer layer is present.

5           The shield 11 (not shown) in the belt 12 of Figure 7 is in the form of a flexible conductive layer, with an insulated undersurface that overlies the circuitry on the outer side portion of the belt 12. This shielding layer must be close enough to the pickup electrodes 1 to evenly distribute ambient noise signals, and be sufficiently spaced  
10 from the pickup electrode/body interface so as to not detract from signal pickup by the pickup electrodes.

          The pick-up electrodes 1, 1A in Figure 4 are held by the substrate 13 of the belt 12, at a fixed, intervening interval. This interval is dimensioned to permit the electrodes 1 to respectively  
15 overlie electrical nodes (not shown) on the body 3 of a wearer 16 as shown in Figure 8. The belt 12 is held in place by tension developed by connectors, e.g. hook-and-loop fastening means, once positioned on the body 3. While a narrow belt 12 is depicted in Figure 8, a wider belt or vest 15 could carry three, four or more electrodes 1 as shown  
20 in Figure 9.

          In either of the cases of Figures 8 or 9 the capacitive pickup electrode performs with a better signal-to-noise ratio with an enhancer 28 present between the electrode 1 and the body 3 or surface from which a signal is being obtained.

25           An advantage of the invention is that multiple pick-up electrodes can be assembled in a preformatted, fixed array that can be fitted to the body collectively, as a unitary assembly, much as in the manner of donning an article of clothing. This permits a wearer to be "fitted-up" for electrical field measurement in a very short period of  
30 time. Data acquisition can readily be suspended and resumed by the simple act of removing and then re-donning the pre-assembled array. No components need be consumed in this process.

          The electrodes 1 of such a piece of apparel as shown in Figure 9 may feed signals to a radio transmitter 19 carried by the  
35 wearer 16. In this manner an especially convenient form of tele-monitoring can be achieved.

Apart from providing the pickup electrode with an insulative layer that inherently suits its operation in the preferred, separation-insensitive zone, the actual freedom from having to place the pickup electrode in intimate contact with the body whose field is to be sensed, has considerable advantages. These include:

- 1) the pickup electrode need not be tightly fixed at a specific location on the skin. Adhesives are avoided;
- 2) the pickup electrode need not be applied under excessive pressure against the skin. Discomfort is avoided;
- 10 3) the skin need not be prepared to receive the electrode, as by shaving or rubbing;
- 4) an insulative layer, such as a pad or layer of clothing may be present between the electrode and the skin. With the electrode pick-up system operating in the low capacitance regime, the appearance of sweat on the skin does not substantially affect the perceived signal notwithstanding any change in the degree of capacitive coupling; and
- 15 5) an improved signal to noise ratio is achieved.

These are substantial conveniences for patients who must submit to ECG examinations. This is particularly true in respect to extended-period ECG monitoring procedures.

While the use of an enhancer has been demonstrated with a capacitive electrode, the enhancer of the invention is also effective with ohmic electrodes. It is particularly effective with ohmic electrodes when CLP is employed as the cushioning material within the enhancer.

#### CONCLUSION

The foregoing has constituted a description of specific embodiments showing how the invention may be applied and put into use. These embodiments are only exemplary. The invention in its broadest, and more specific aspects, is further described and defined in the claims which now follow.

These claims, and the language used therein, are to be understood in terms of the variants of the invention which have been described. They are not to be restricted to such variants, but are to be read as covering the full scope of the invention as is implicit within the invention and the disclosure that has been provided herein.

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE  
PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. A bio-electrode for sensing body electrical fields fitted  
with an enhancement layer on the body-side of the electrode wherein the  
5 enhancement layer:
  - 1) has electrical conductivity which provides electrical  
conduction between the body and the electrode;
  - 2) has the capacity to contain water; and
  - 3) emanates water through its outer body-facing surface when  
10 water is contained therein to thereby quiet tribo-electric  
effects.
2. A bio-electrode as in claim 1 comprising:
  - 1) a capacitive electrode plate;
  - 2) an insulative dielectric layer positioned against the  
15 electrode plate;wherein the enhancement layer is positioned against the dielectric  
layer.
3. A bio-electrode as in claims 1 or 2 wherein the enhancement  
layer:
  - 20 1) has an outer body-facing surface that is non-slippery so as  
to engage with a surface whose field is to be sensed  
sufficiently to resist displacements at the enhancement  
layer to surface interface when the electrode plate is  
subjected to slight displacements; and
  - 25 2) comprises a "cushioning" character that allows for slight  
displacements of the electrode with respect to the body  
without significant disruption of the mechanical interfaces  
between the body and the layer, and between the layer and  
the electrode.
- 30 4. A bio-electrode as in claims 1 or 2 wherein the enhancement  
layer upon being wetted with water becomes moisture-emanating and  
permits moisture to be released into the enhancement layer-to-body

interface improving conduction between the body signal source and the electrode.

5. A bio-electrode as in claims 1 or 2 wherein the enhancement layer comprises a super water absorbent polymer present therein to  
5 slowly release an effective quantity of water into the body-to-electrode interface.

6. A bio-electrode as in claim 5 wherein the polymer is selected from the group consisting of sodium polyacrylate/polyacrylamide and potassium polyacrylate copolymer, potassium  
10 polyacrylamide or mixtures thereof.

7. A bio-electrode as in claims 5 or 6 wherein the polymer is in the form of granules contained in a water permeable bag of fabric.

8. A bio-electrode as in claims 1 or 2 wherein the enhancement layer displays a bulk resistance between the electrode and a body of  
15 less than 10 Megohms.

9. A bio-electrode as in claim 1, 2, 3, 4, 5, 6, 7 or 8 in combination with clothing layers overlying a body wherein the enhancement layer is applied over the clothing layers.

10. A bio-electrode as in claims 1 or 2 wherein the enhancement  
20 layer's electrical conductivity is derived from ionic conductivity.

11. A bio-electrode as in claim 10 wherein the enhancement layer comprises a conductive fluid selected from the group consisting of a mild solution of sodium chloride, magnesium chloride, lithium chloride or mixtures thereof having ionic conductivity and body-compatible  
25 properties.

12. A bio-electrode as in claims 2, 3, 4, 5, 6, 7, 8, 9, 10 or 11 wherein the electrode is a capacitive electrode coupled to an electronic sensing circuitry means and the input capacitance between



the body to be sensed and such electronic sensing means operates in the region of the relationship  $C=eA/d$  where capacitance  $C$  is relatively insensitive to variations in separation gap  $d$ .

5 13. A bio-electrode as in claim 12 wherein a 0.1 mm displacement of the electrode causes less than a 50 percent change in the value of  $C$ :

10 14. A bio-electrode as in claim 12 wherein the electrode is provided with an insulating, dielectric layer of a thickness that precludes the electrode from providing a capacitance of more than 10 picoFarads/square centimeter.

15 15. A bio-electrode as in claim 12 wherein said electronic sensing circuitry means comprises an input series capacitance of less than substantially 20 picoFarads placed in series with the electrode to make the signal pickup relatively non-dependent on the intimacy of the electrode contact with the body.

20 16. A bio-electrode as in claim 12, 13, 14, 15 or 16 wherein the electronic circuit sensing means has an input capacitance of less than 25 picoFarads.

17. A bio-electrode as in claim 12, 13, 14, 15 or 16 wherein the electronic circuit sensing means has an input capacitance of less than 15 picoFarads.

25 18. A bio-electrode as in claim 12, 13, 14, 15 or 16 wherein the electronic circuit sensing means has an input capacitance of less than 10 picoFarads.

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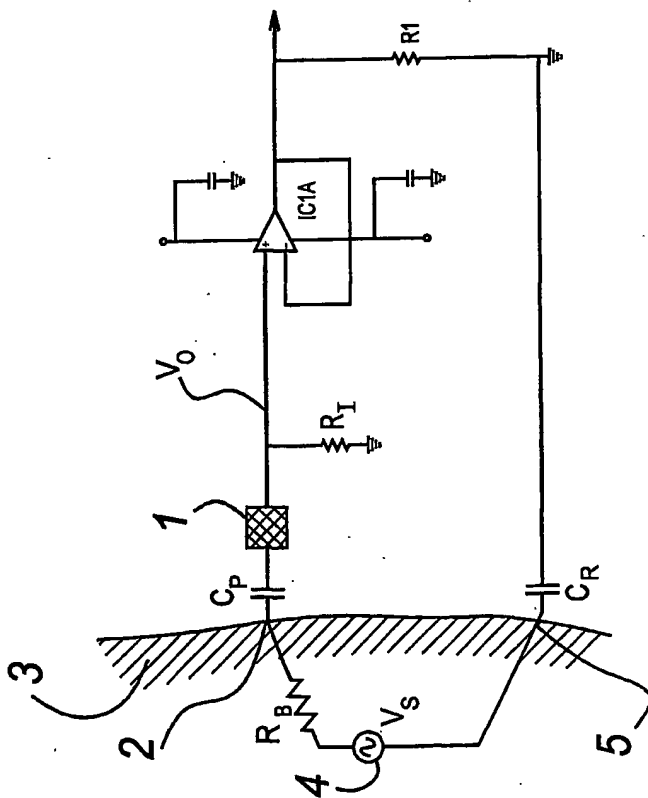


FIG. 1A

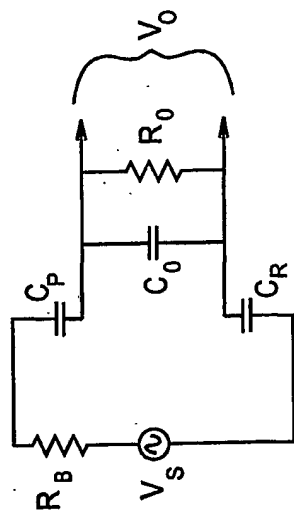


FIG. 1B

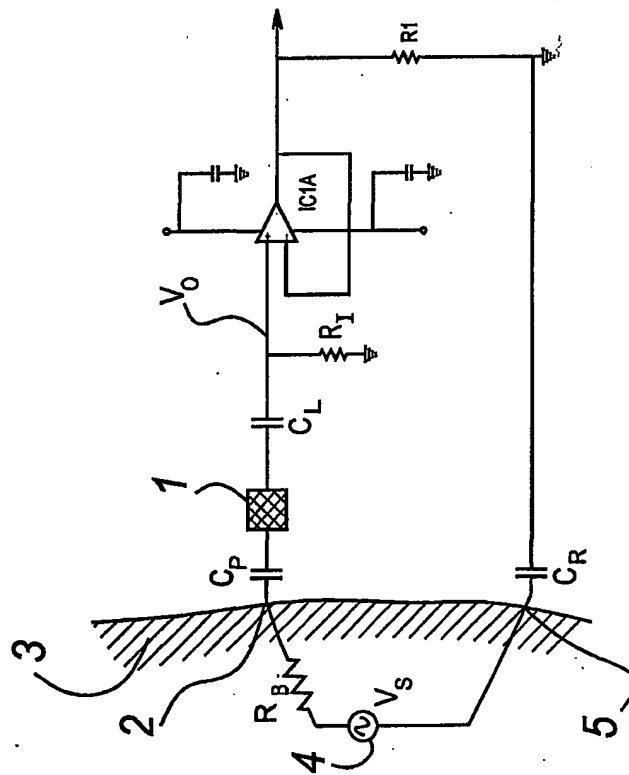


FIG. 1C

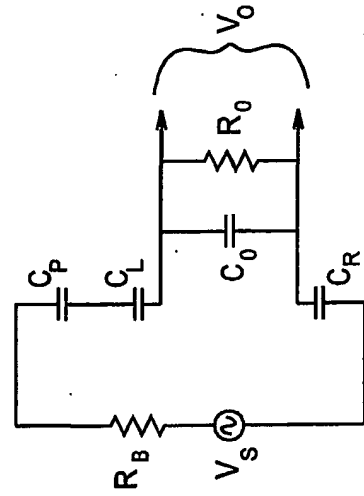


FIG. 1D

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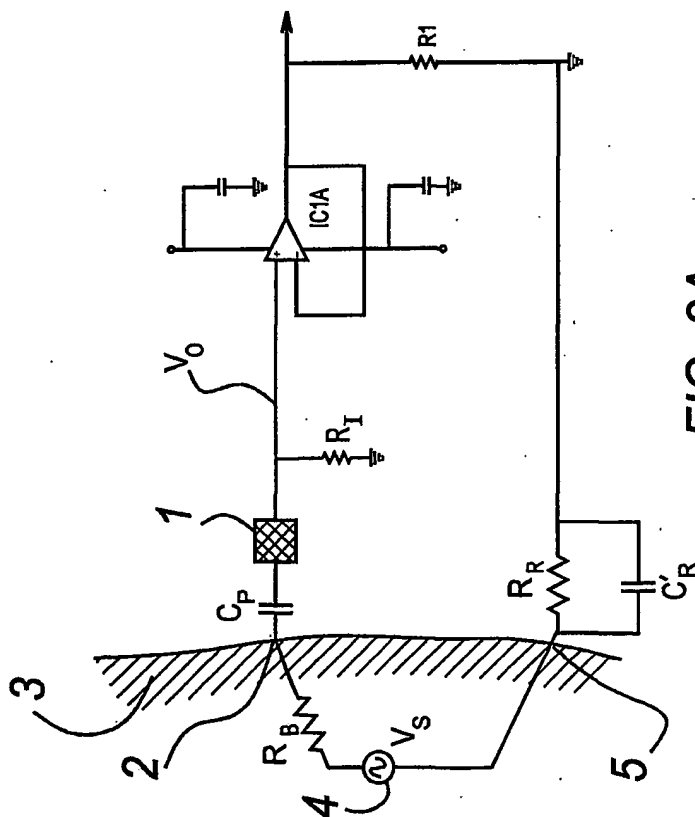


FIG. 2A

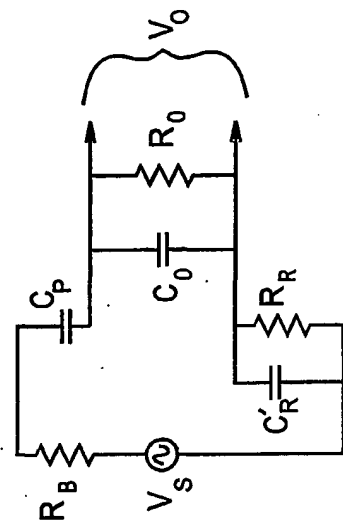


FIG. 2B

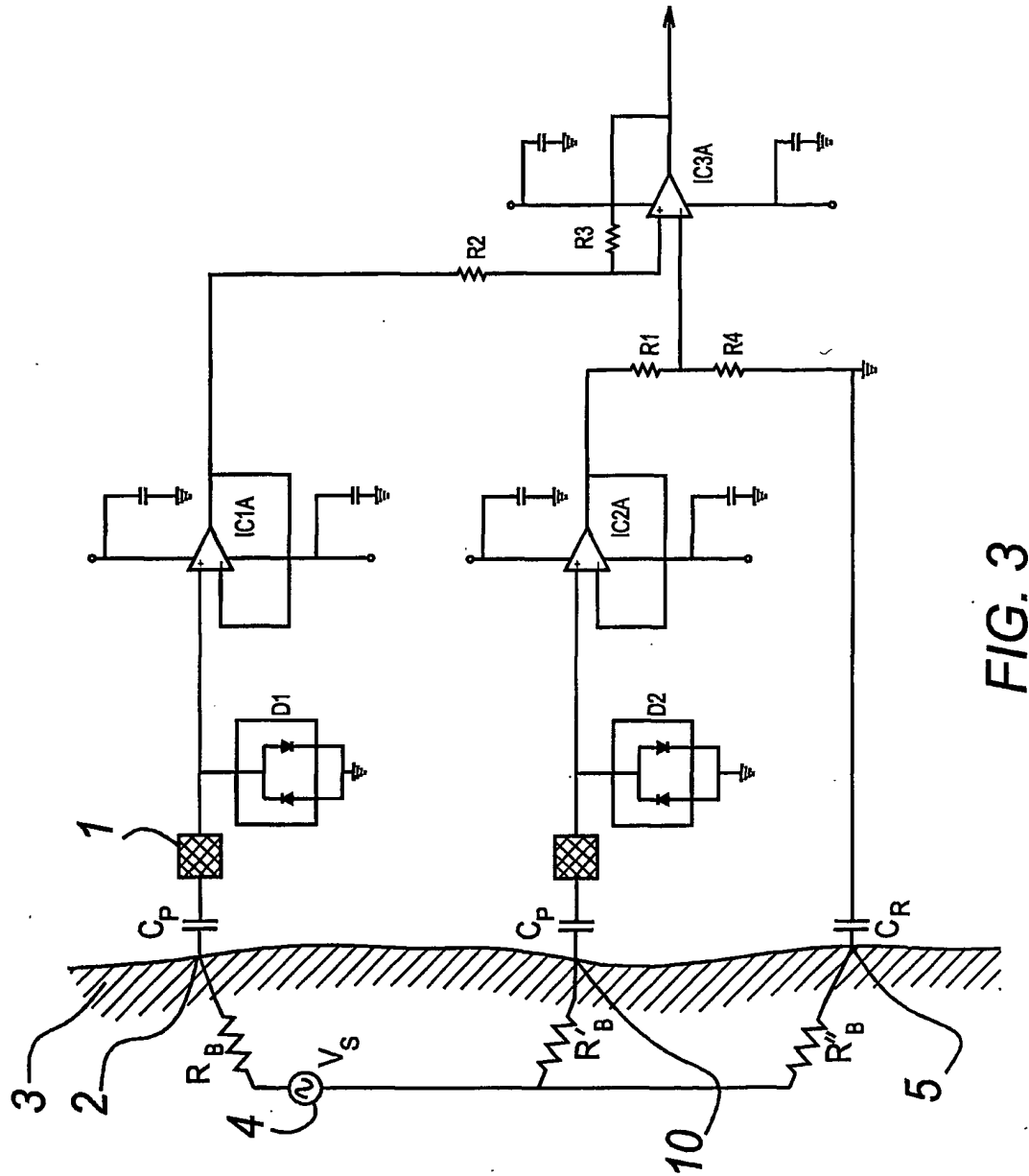
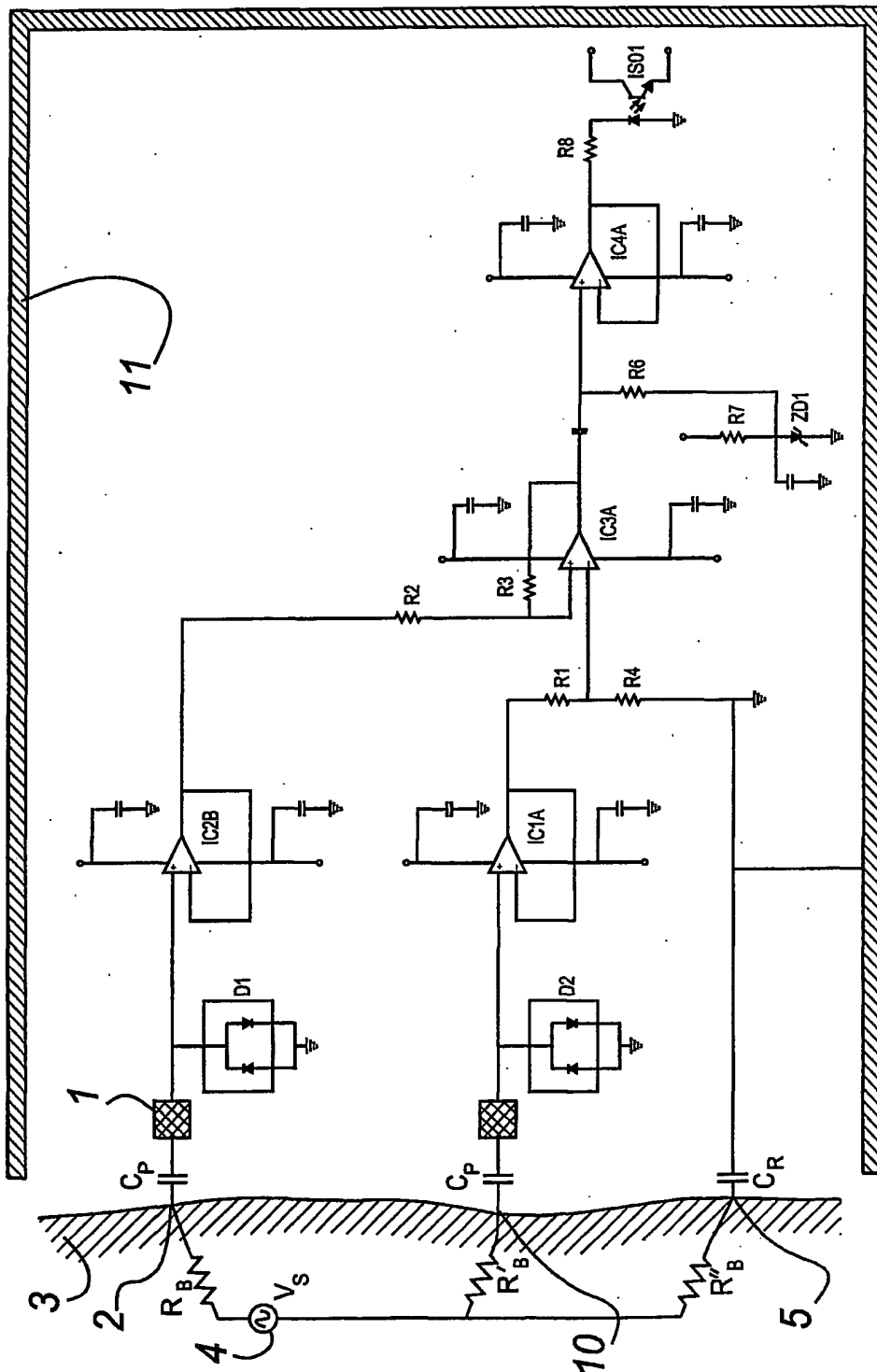
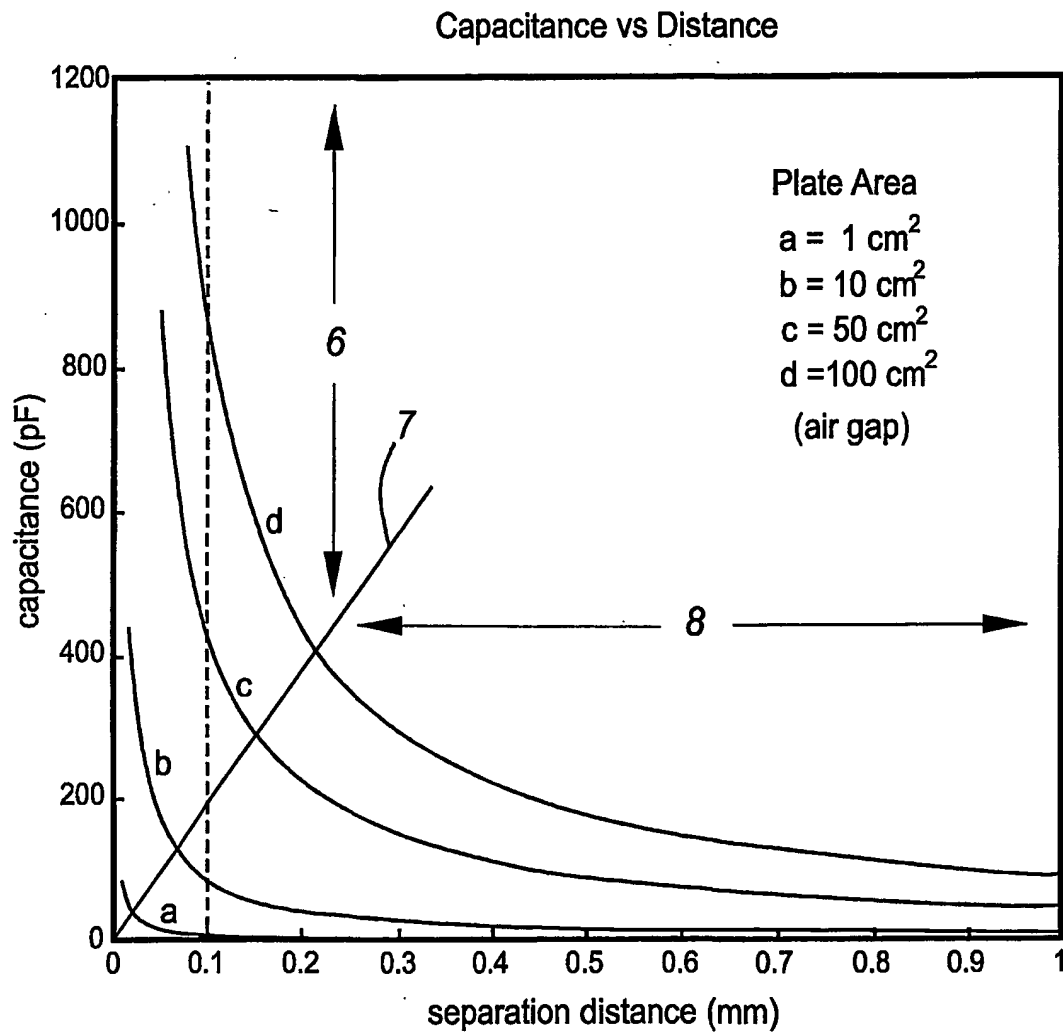


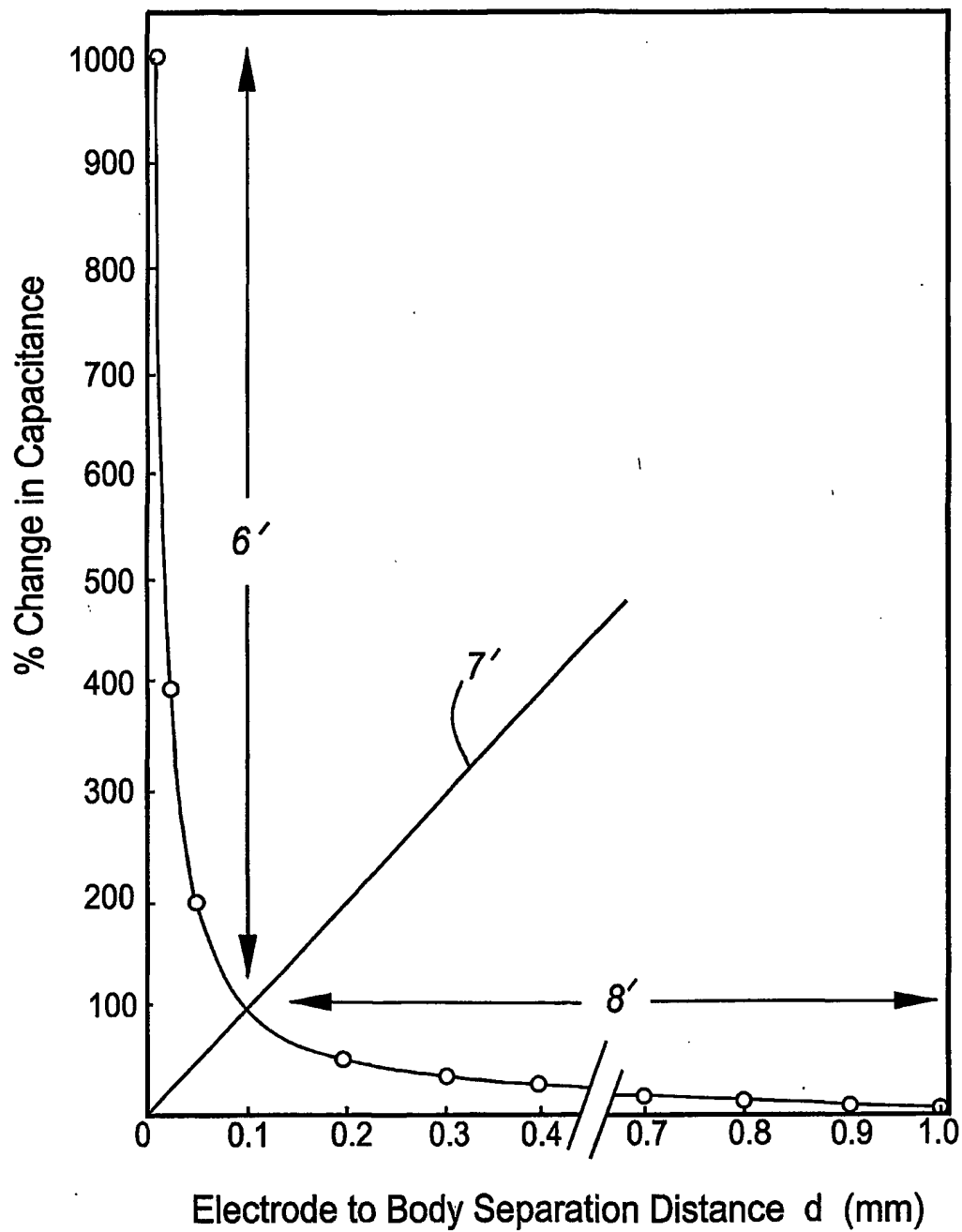
FIG. 3



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**FIG. 5**

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**FIG. 6**



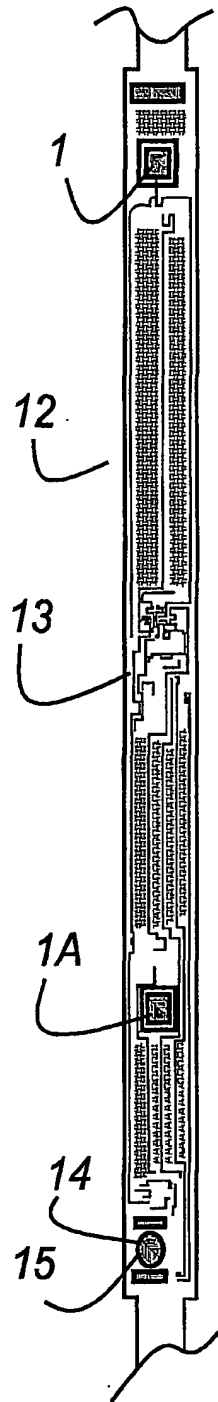


FIG. 7

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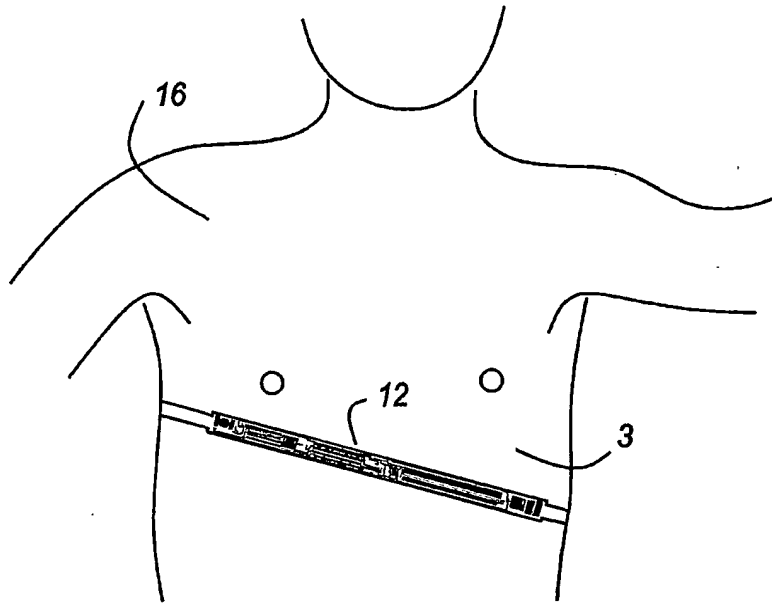


FIG. 8

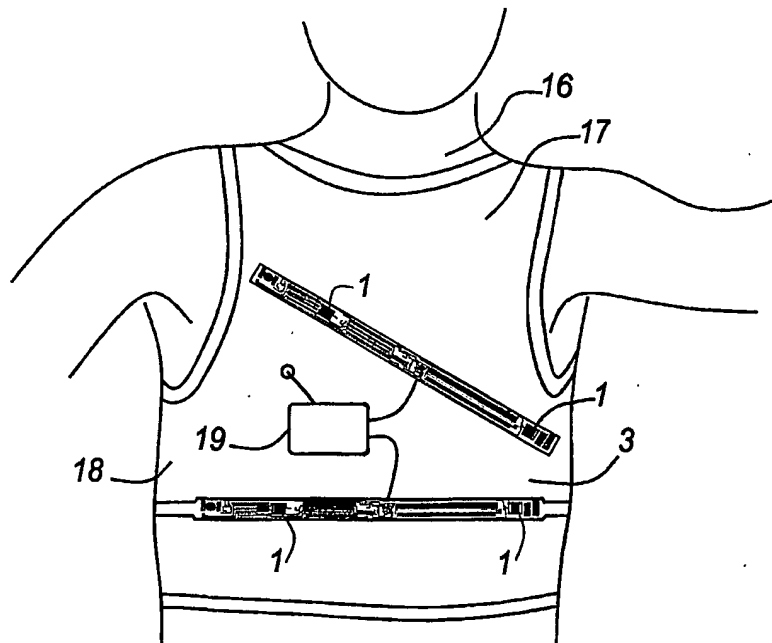
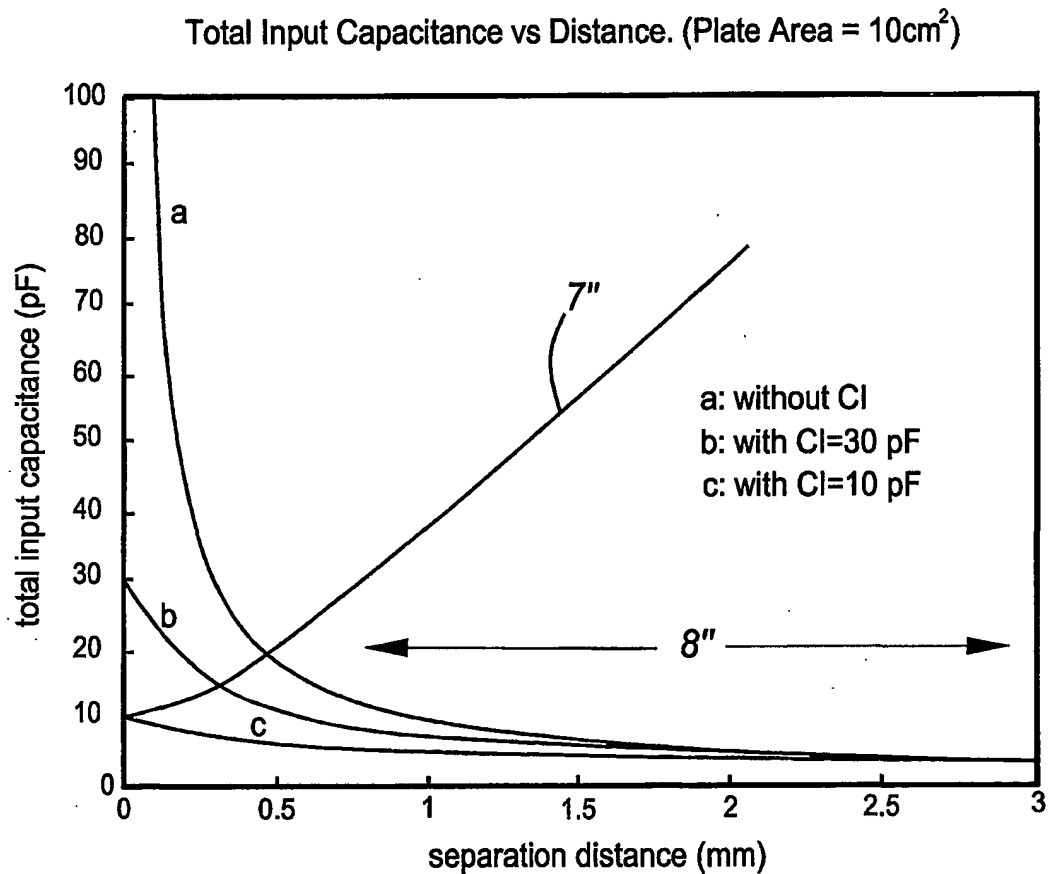
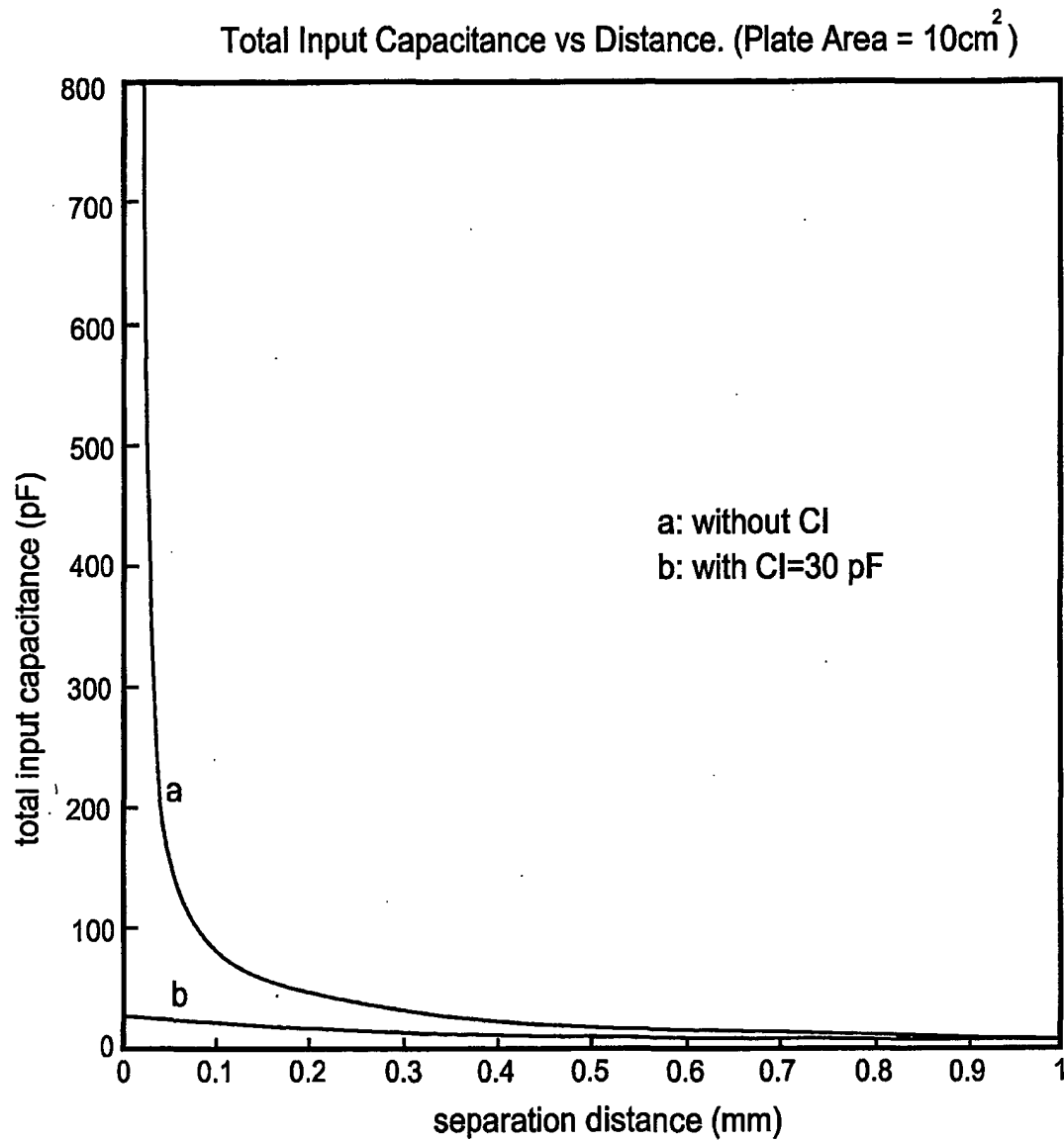


FIG. 9

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**FIG. 10**

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**FIG. 11**

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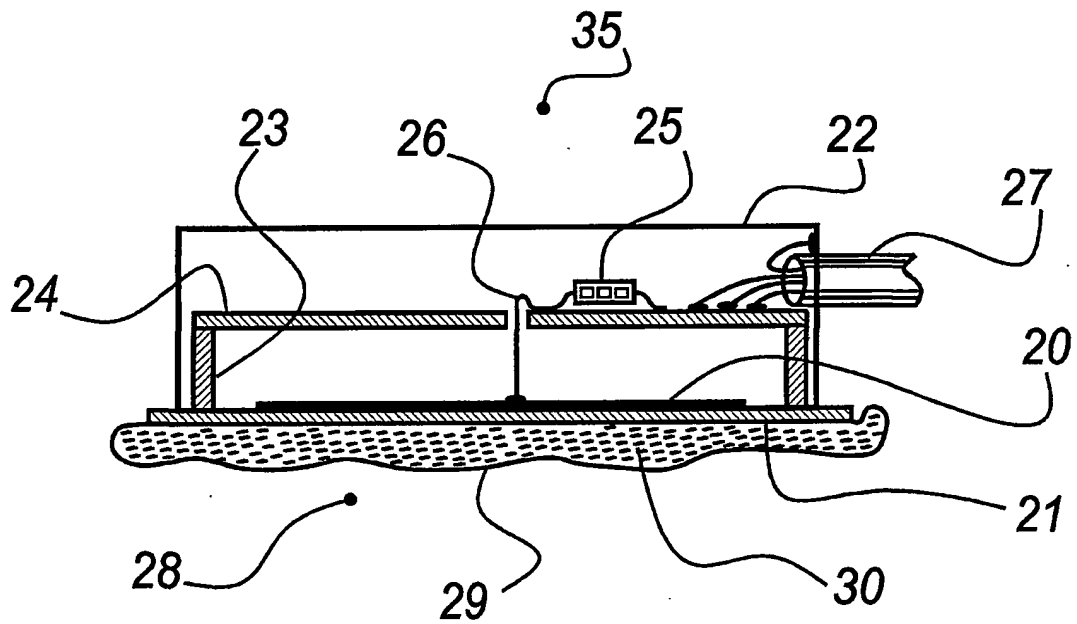


FIG. 12

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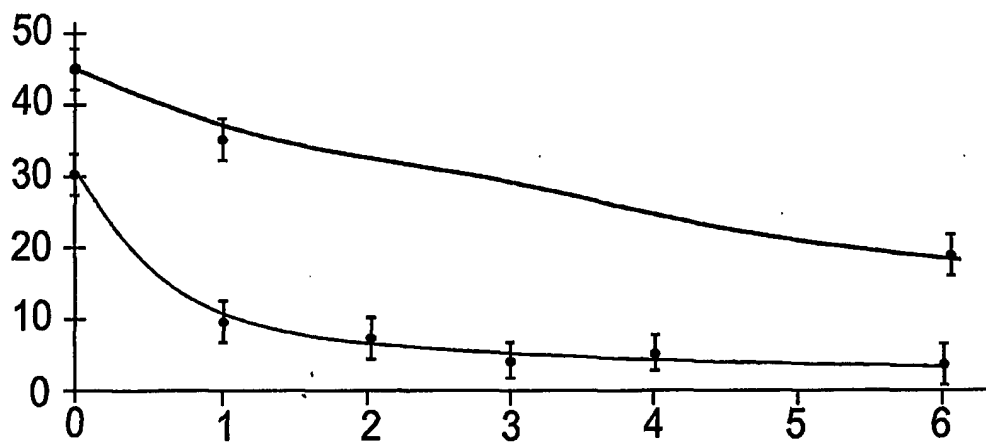


FIG. 13

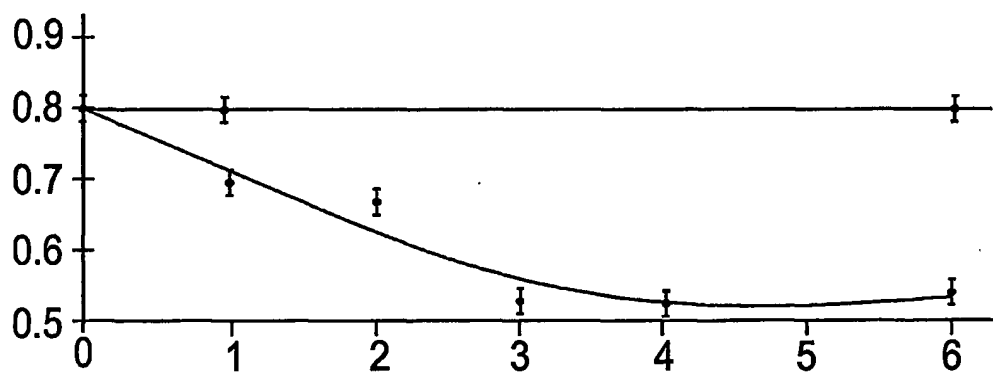
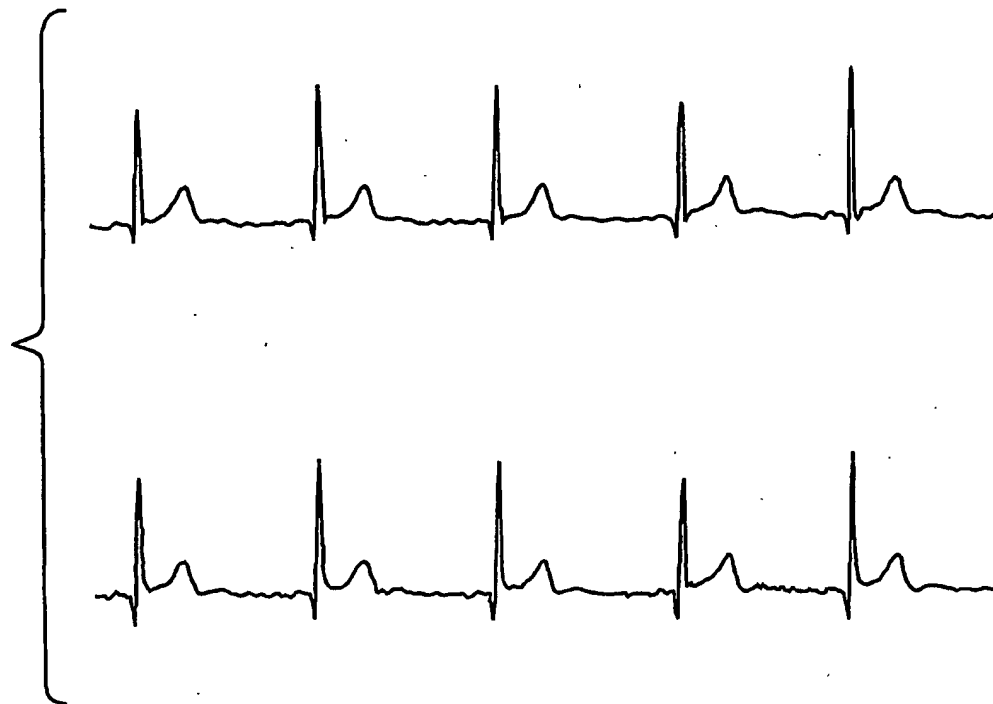
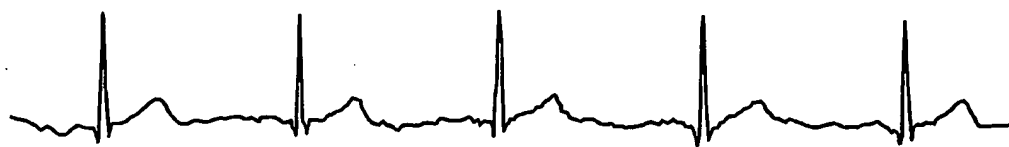


FIG. 14

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**FIG. 15**



**FIG. 16**

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**FIG. 17**



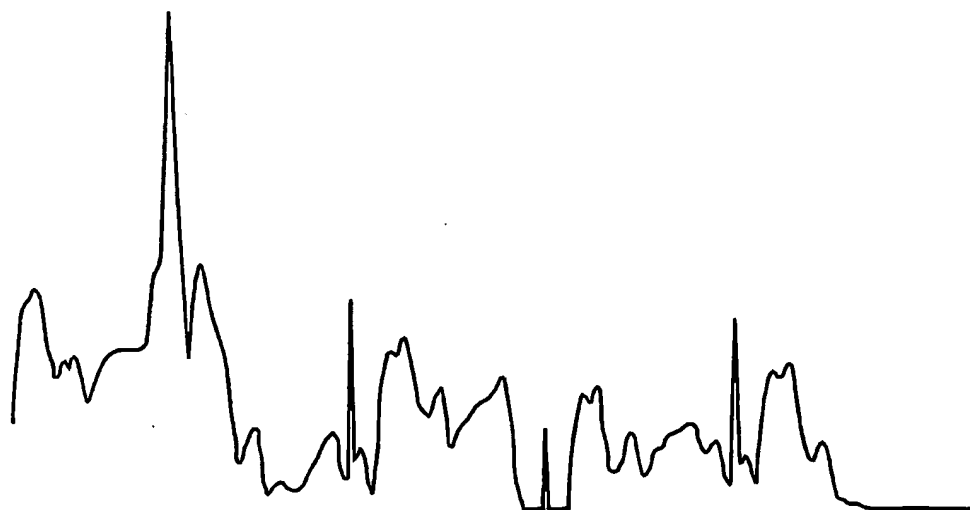
**FIG. 18**



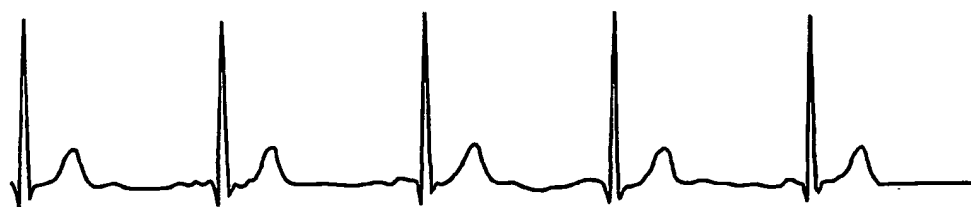
**FIG. 19**



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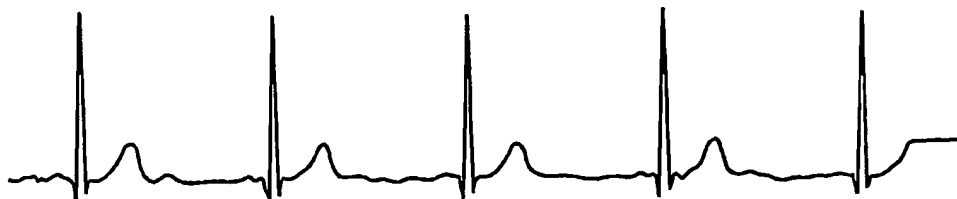


**FIG. 20**

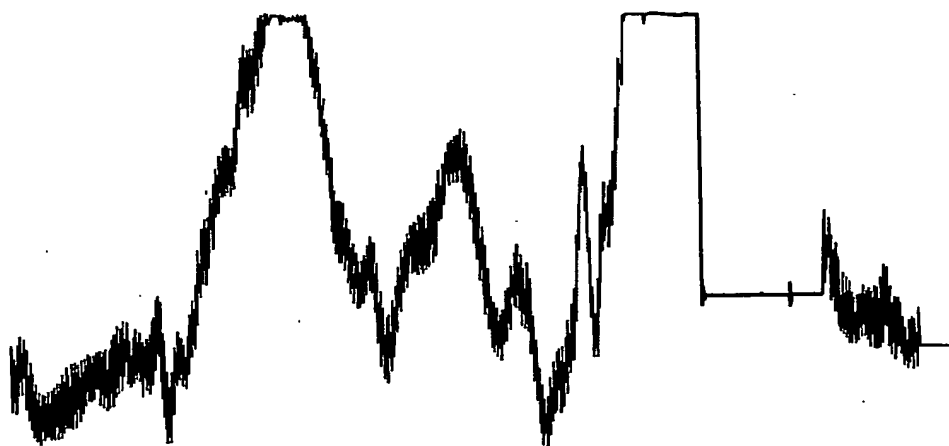


**FIG. 21**

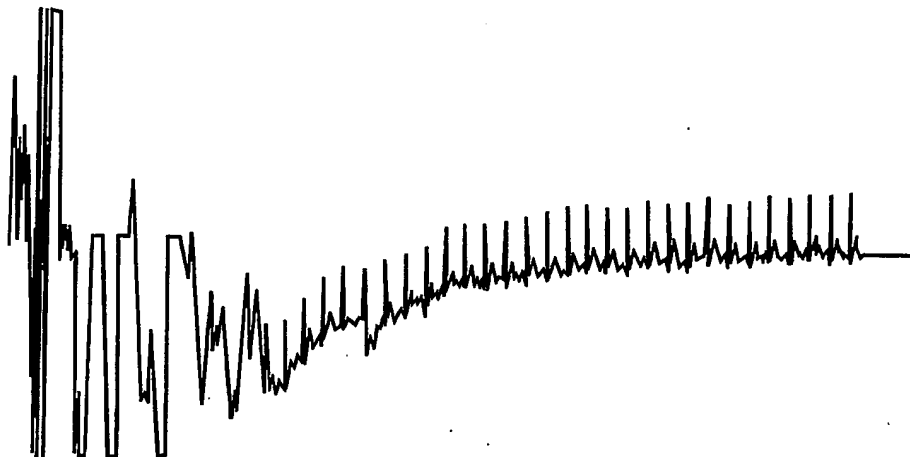
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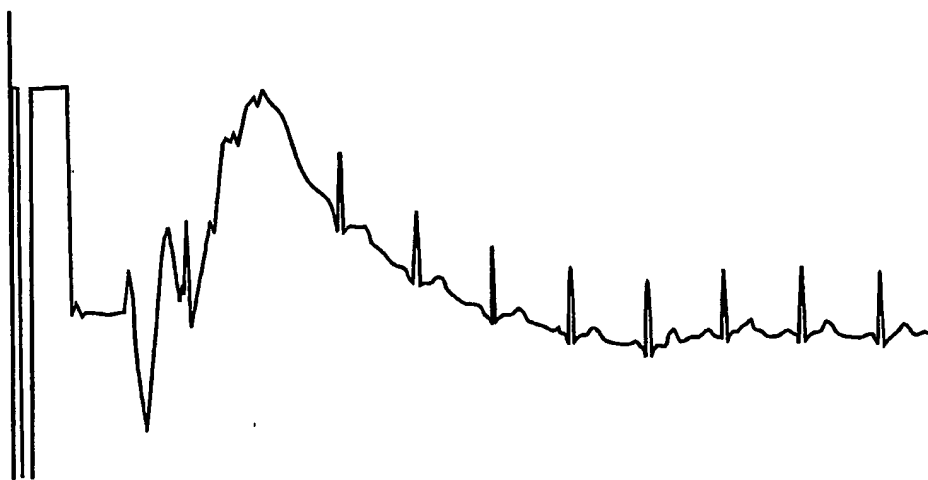
*FIG. 22*



*FIG. 23*



*FIG. 24*



*FIG. 25*

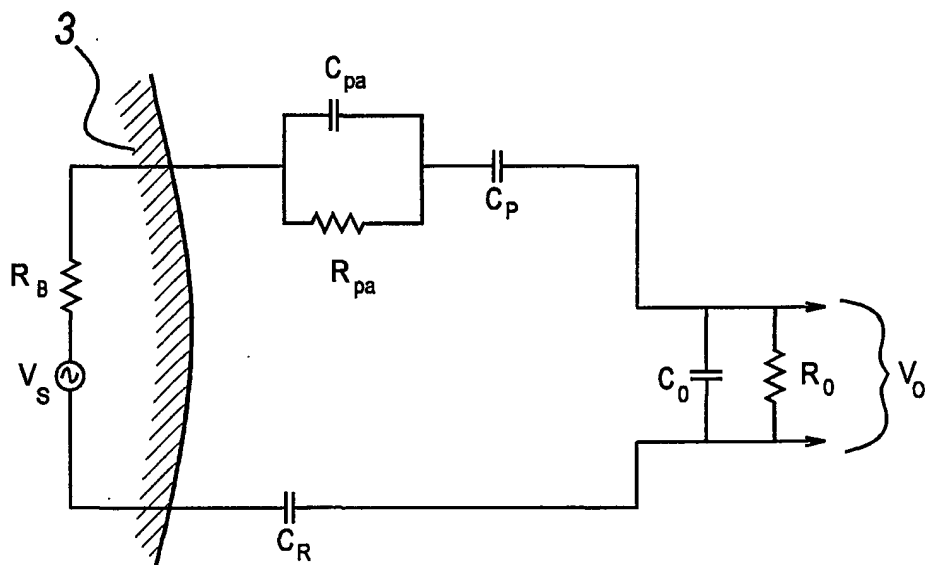


FIG. 26

# INTERNATIONAL SEARCH REPORT

Intern:                      Application No  
PCT/CA 01/00217

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC 7    A61B5/0408		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) IPC 7    A61B    A61N		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 795 293 A ( H. M. CARIM ET AL ) 18 August 1998 (1998-08-18) cited in the application	1,3-7
A	column 1, line 13 -column 4, line 25	8-18
Y	US 5 289 822 A ( A. J. HIGHE ET AL ) 1 March 1994 (1994-03-01) column 2, line 38 -column 3, line 40	1,3-7
Y	US 5 645 527 A ( J. E. BECK ) 8 July 1997 (1997-07-08) cited in the application	1,3-7
A	column 1, line 13 -column 6, line 40 column 9, line 15 -column 10, line 9	8-18
Y	US 5 947 920 A ( J. E. BECK ) 7 September 1999 (1999-09-07) abstract	1,3-7
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<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.		
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Date of the actual completion of the international search 17 October 2001		Date of mailing of the international search report 24/10/2001
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer Geffen, N

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 846 185 A ( H. M. CARIM ) 11 July 1989 (1989-07-11) column 3, line 25 -column 5, line 27 -----	1-18
A	US 4 692 273 A ( K. LAWRENCE ) 8 September 1987 (1987-09-08) the whole document -----	1-18

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Internal Application No

PCT/CA 01/00217

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5795293	A	18-08-1998	WO 9724060 A1	10-07-1997
US 5289822	A	01-03-1994	NONE	
US 5645527	A	08-07-1997	AU 697890 B2	22-10-1998
			AU 1052697 A	28-08-1997
			CA 2243319 A1	14-08-1997
			EP 0957778 A1	24-11-1999
			JP 11503956 T	06-04-1999
			WO 9728748 A1	14-08-1997
US 5947920	A	07-09-1999	AU 720011 B2	18-05-2000
			AU 6701298 A	12-10-1998
			EP 0969899 A1	12-01-2000
			JP 2000516833 T	19-12-2000
			TW 430567 B	21-04-2001
			WO 9841280 A1	24-09-1998
US 4846185	A	11-07-1989	NONE	
US 4692273	A	08-09-1987	NONE	

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